
524-576


009268382



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

NOTICE OF PESTICIDE REGISTRATION

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

EPA Reg.
Number:
524-576

Date of Issuance:
6/10/88

Term of
Issuance:

**Conditional
Time- Limited**

Name of Pesticide Product:

MON 89034 x MON 88017

Name and Address of Registrant (include ZIP Code):

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

- 1) The subject registration will automatically expire on midnight September 30, 2010.
- 2) The subject registration will be limited to MON 89034 x MON 88017 in field or sweet corn. Further, MON 89034 x MON 88017 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 x MON 88017 sweet corn may not be sold to small roadside or home growers
- 3) Submit/cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires registrants of similar products to submit such data.

Signature of Approving Official:

See last page JEA

Janet Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division (7511P)

Date:

6/10/88



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

NOTICE OF PESTICIDE REGISTRATION

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

EPA Reg.
Number:
524-576

Date of Issuance:

6/10/08

Term of
Issuance:

Conditional
Time- Limited

Name of Pesticide Product:

MON 89034 x MON 88017

Name and Address of Registrant (include ZIP Code):

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

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Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

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- 1) The subject registration will automatically expire on midnight September 30, 2010.
- 2) The subject registration will be limited to MON 89034 x MON 88017 in field or sweet corn. Further, MON 89034 x MON 88017 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 x MON 88017 sweet corn may not be sold to small roadside or home growers
- 3) Submit/cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires registrants of similar products to submit such data.

Signature of Approving Official:

Janet Andersen
Janet Andersen, Ph.D., Director

Date:

6/10/08

Biopesticides and Pollution Prevention Division (7511P)

CONCURRENCES

SYMBOL	EPA FORM 8570-6	7511P	7511P					
SURNAME		<i>Scoville</i>	<i>Miller</i>					
DATE		6/10/08	6/11/08					2

4) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
860.1340 Residue Analytical method - Plants	For event MON 89034 x MON 88017 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105. The registrant must also agree to provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	4/1/2009
850.1010 Aquatic Invertebrate Acute Toxicity Testing, Freshwater <i>Daphnia</i>	A 7 to 14 day <i>Daphnia</i> study as per the 885 Series OPPTS Guidelines needs to be performed. Alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams, can be performed and submitted in lieu of the <i>Daphnia</i> study.	4/1/2009
Insect Resistance Management	Monsanto did not address the likelihood of cross-resistance of Cry1A.t05, Cry1Ac, Cry1Fa, proteins already in existing Bt corn and Bt cotton products, and what impact such cross-resistance would have on the durability of MON 89034. Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.t05 and Cry1Ac and Cry1Fa.	4/t/2009 Protocol Due 8/1/2008
Insect Resistance Management	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.	4/1/2009

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management	To support sweet corn uses, baseline susceptibility studies must be conducted on FAW populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2010

5) Submit or cite all data required to support the individual plant-incorporated protectant in Event MON863 (YieldGard Rootworm), 524-528. In the event that the Agency concludes MON 863 (YieldGard Rootworm) studies do not sufficiently demonstrate a lack of significant adverse effects, additional data with MON 88017 corn must be submitted. This data may include a) laboratory toxicity testing with *Orius insidiosus* (minute pirate bug), b) laboratory toxicity testing with a carabid (ground beetle), c) long range effects testing on invertebrate populations in the field, and d) long range soil persistence testing.

6) You must implement the following Insect Resistance Management Program for MON 89034 x MON 88017.

a) Refuge Requirements for MON 89034 x MON 88017

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn nor to commercial hybrid sweet corn.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements or, in the case of sweet corn, harvest practices as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

For MON 89034 x MON 88017 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

Two options for deployment of the refuge are available to growers. The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and refuge acres). It can be planted as a block adjacent to the [MON 88017 x MON 89034] field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late

season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 89034] field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and corn borer refuge acres); and must be planted within ½ mile of the [MON 88017 x MON 89034] field. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. The corn rootworm refuge must be planted with a non-Bt/corn rootworm-protected hybrid, but can be planted with Bt corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and corn rootworm refuge acres) and can be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 89034] field must be treated in a similar manner. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

b) Grower Agreements for MON 89034 x MON 88017

- i. Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- ii. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- iii. The registrant must integrate this registration into the current system used for their other Bt corn PIPS to reasonably likely to assure that persons purchasing the Bt corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description must be submitted to EPA by August 1, 2008.
- iv. The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to

EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

- v. The registrant must integrate this registration into the current system to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system. A description must be submitted to EPA by August 1, 2008.
- vi. The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- vii. Beginning on January 31, 2010 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON 89034 x MON 88017 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve month period covering the prior August through July.
- viii. The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Programs for MON 89034 x MON 88017

- i. Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON 89034 x MON 88017 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 89034 x MON 88017 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 89034 x MON 88017 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON 89034 x MON 88017 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
- ii. Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph vi. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- iii. On January 31, 2010, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report.

The required features of the compliance assurance program are described in paragraphs iv.-xv. below.

- iv. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 89034 x MON 88017 Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON 89034 x MON 88017 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other Bt corn PIPS. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program. Other required features of the program are described in paragraphs v. -- xv. below.
- v. The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of noncompliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of Monsanto corn PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto corn PIP products
- vi. The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S. The survey will include only growers planting at least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.
- vii. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- viii. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- ix. The registrant shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.

- x. Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.
- xi. The registrant shall train its representatives who make on-farm visits with MON89034 x MON 88017 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance. This on-farm assessment program has no minimum acreage threshold for growers.
- xii. The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- xiii. If a grower, who purchases MON 89034 x MON 88017 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- xiv. Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- xv. The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d) Insect Resistance Monitoring for MON 89034 x MON 88017

The Agency is imposing the following conditions for this product:

- i. Post-commercial resistance monitoring programs must be established as an extension of existing programs to track the susceptibility of the key lepidopteran corn pests to the Cry1A.105 and Cry2Ab2 proteins. For the Cry1A.105 and Cry2Ab2 proteins, the registrant will monitor for resistance and/or trends in increased tolerance for European corn borer, Southwestern corn borer, and corn earworm. Sampling should be focused in those areas in which there is the highest risk of

resistance development. Monitoring must be carried out under the same protocols used for the products containing MON 810. Sampling should be focused in those areas in which there is the highest risk of resistance development. In the monitoring program, insect populations will be collected and each protein will be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

- ii. In addition to monitoring ECB, SWCB, and CEW, Monsanto will develop and ensure the implementation for resistance monitoring for *Spodoptera frugiperda* (fall armyworm of FAW) in counties which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. The registrant should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which MON 89034/ MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.
- iii. For the Cry3Bb1 portion of the product, a revised Cry3Bb1 monitoring plan that incorporates MON 89034 x MON 88017 must be submitted to the Agency within 90 days of the date of registration.
- iv. For the Cry3Bb1 portion of the product, the registrant must develop and validate an appropriate discriminating or diagnostic dose assay by January 31, 2010.
- v. For the Cry3Bb1 portion of the product, the registrant must finalize rootworm damage guidelines and submit these to BPPD by January 31, 2010.
- vi. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- vii. The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2010, reporting on populations collected the previous year.

e) Remedial Action Plans for MON 89034 x MON 88017

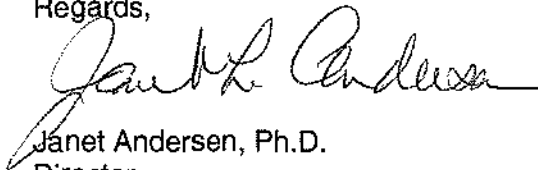
The October 15, 2001 Remedial Action Plan for Responding to Resistance in European Corn Borer, Corn Earworm and/or Southwestern Corn Borer must be used for suspected and confirmed resistance of these pests. The current remedial action plan approved for MON 863 must be used for corn rootworm suspected and confirmed resistance in [MON 89034 x MON 88017]. If corn rootworm resistance is confirmed, all acres ([MON 89034 x MON 88017] and refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

The annual reporting requirements are as follows:

- i. Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- ii. Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- iii. Grower Education: substantive changes to education program completed previous year, January 31st each year;
- iv. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- v. Compliance: to include annual survey results and plans for the next year; full report, January 31st each year;
- vi. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August, 31st each year.

A stamped copy of the label is enclosed for your records.

Regards,



Janet Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division

Plant-Incorporated Protectant Label

MON 89034 x MON 88017

Lepidopteran-and Rootworm-Protected Corn
(OECD Unique Identifier: MON-89034-3 x MON 88017-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3).....0.001-0.0024%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3).....0.0030-0.0057%

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON 88017-3).....0.0037-0.0070%

Inert Ingredient:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and genetic material necessary (vector PV-ZMIR39) for its production in event MON 88017 corn (OECD Unique Identifier: MON 88017-3).....0.0038-0.0069%

Percentage (wt/wt) on a dry weight basis whole plant (forage)

Caution

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-576

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

ACCEPTED

JUN 10 2008

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 524-576

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

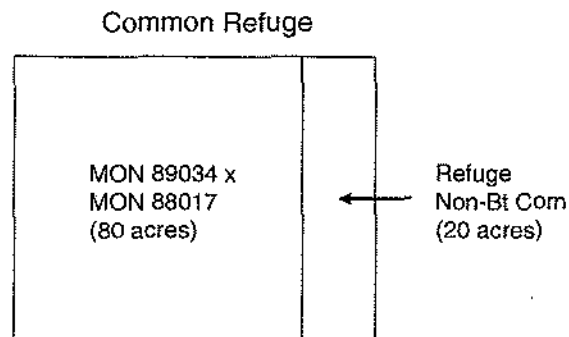
MON 89034 x MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 x MON 88017 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid sweet corn.

For MON 89034 x MON 88017 sweet corn, growers are required to destroy any MON 89034 x MON 88017 sweet corn stalks that remain in the field following harvest via rotary mowing, disking, or plow-down within one (1) month of harvest.

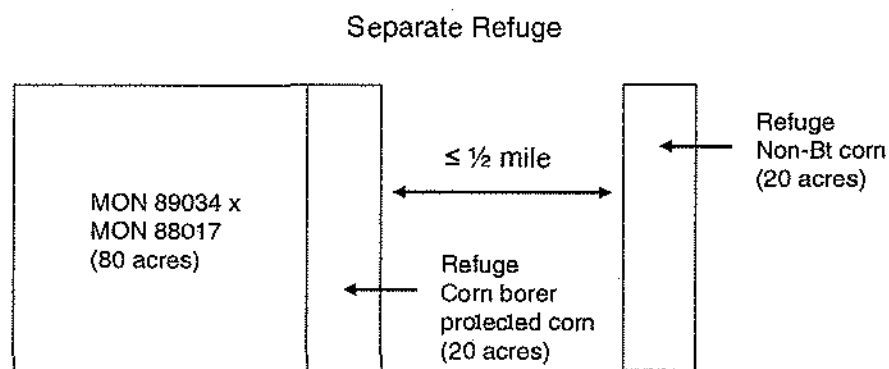
For MON 89034 x MON 88017 field corn, two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of MON 89034 x MON 88017 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted). It can be planted as block within or adjacent (e.g., across the road) to the MON 89034 x MON 88017 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for the control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field (acres) must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



The second option is planting separate refuge areas (e.g., two refuge areas, a double refuge, or paired refuge areas) for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 20% of the grower's corn acres, and must be planted within ½ mile of the MON 89034 x MON 88017 field. Refuge planting options include: separate fields, blocks within fields (e.g. along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 rows wide. The corn borer refuge can be treated with an insecticide for corn rootworm larval control, or a non-Bt foliar applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, but can be planted with Bt hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., corn rootworm refuge must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted) and can be planted as a block within or adjacent to the MON 89034 x MON 88017 field, strips around the field, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 rows wide. The corn rootworm refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if corn rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field must be treated in a similar manner. A schematic of one separate refuge option with the corn rootworm refuge planted as a block within the field and the corn borer refuge planted within a ½ mile of the MON 89034 x MON 88017 field is shown below:



Corn Insects Controlled

European corn borer	<i>Ostrinia nubilalis</i>
Southwestern corn borer	<i>Diatraea grandiosella</i>
Southern cornstalk borer	<i>Diatraea crambidoides</i>
Corn earworm	<i>Helicoverpa zea</i>
Fall armyworm	<i>Spodoptera frugiperda</i>
Corn stalk borer	<i>Papaipema nebris</i>
Sugarcane borer	<i>Diatraea saccharalis</i>
Western corn rootworm	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm	<i>Diabrotica barberi</i>
Mexican corn rootworm	<i>Diabrotica virgifera zeae</i>

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated protectant must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 x MON 88017 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.



"SCHNEIDER,
RUSSELL P
[AG/1920]"
<russell.p.schneider
@monsanto.com>

06/10/2008 12:20
PM

To: Susanne Cerrelli/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Alan
Reynolds/DC/USEPA/US@EPA
cc
bcc
Subject: Release

The November 7, 2007 Review of Human Health and Product Characterization Data for Registration of *B. thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material Necessary for their Production in MON 89034 and the November 8, 2007 Review of Human Health and Product Characterization Data for Registration of *B. thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material Necessary for their Production in MON 89034 X MON 88017 corn, are not Confidential Business Information and may be placed in the docket for review.

Thanks,

Russ

Dr. Russell P. Schneider

Senior Director, Regulatory Affairs and Policy

Monsanto Company

1300 I St., NW

Suite 450 East

Washington, DC 20005

202/383-2866

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"SCHNEIDER,
RUSSELL P [AG/1920]"
<russell.p.schneider@m
onsanto.com>

06/10/2008 07:02 AM

To: Susanne Cerrelli/DC/USEPA/US@EPA, Alan
Reynolds/DC/USEPA/US@EPA

cc

bcc

Subject: FW: labels

Per the last email message from Alan late yesterday, attached is the revised label for the stack. Also Susanne, please note, both labels include the OECD unique identifier.

Russ

<<MON 89034xMON88017 assembled part 1.doc>> <<MON 89034 assembled
May2008.doc>>

This e-mail message may contain privileged and/or confidential information, and is intended to be received only by persons entitled to receive such information. If you have received this e-mail in error, please notify the sender immediately. Please delete it and all attachments from any servers, hard drives or any other media. Other use of this e-mail by you is strictly prohibited.

All e-mails and attachments sent and received are subject to monitoring, reading and archival by Monsanto, including its subsidiaries. The recipient of this e-mail is solely responsible for checking for the presence of "Viruses" or other "Malware". Monsanto, along with its subsidiaries, accepts no liability for any damage caused by any such code transmitted by or accompanying this e-mail or any attachment.



MON 89034xMON88017 assembled part 1.doc MON 89034 assembled May2008.doc

Plant-Incorporated Protectant Label

MON 89034

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89034-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.002-0.0056%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0015-0.0055%

Percentage (wt/wt) on a dry weight basis whole plant (forage)

Caution

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-LTL

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

MON 89034 can be crossed with MON 88017 for breeding purposes to produce MON 89034 x MON 88017

In order to minimize the risk of these pests developing resistance to MON 89034 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

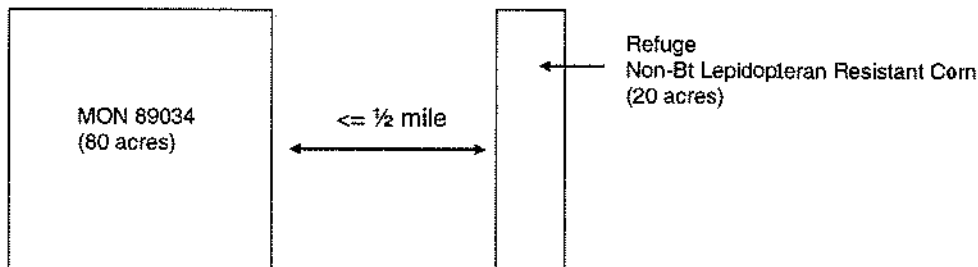
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid sweet corn.

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, disking, or plow-down within one (1) month of harvest.

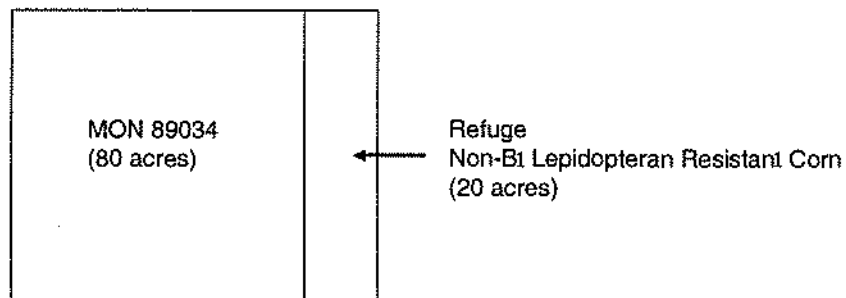
For MON 89034 field corn, grower guides must specify that growers must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% corn which is not a lepidopteran-protected Bt corn. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least 4 rows wide.



Insecticide treatments for control of European corn borer, corn earworm, and Southwestern corn borer, cornstalk borer, sugarcane borer, fall armyworm and stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or

regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

Corn Insects Controlled

European corn borer	<i>Ostrinia nubilalis</i>
Southwestern corn borer	<i>Diatraea grandiosella</i>
Southern cornstalk borer	<i>Diatraea crambidoides</i>
Corn earworm	<i>Helicoverpa zea</i>
Fall armyworm	<i>Spodoptera frugiperda</i>
Corn stalk borer	<i>Papaipema nebris</i>
Sugarcane borer	<i>Diatraea saccharalis</i>

Plant-microbe pest control

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 6018100, 6051753, 6331665, 6489542, 6645497, 6962705, 7064249, and 7250501.

6/10/08 amended

Plant-Incorporated Protectant Label

MON 89034 x MON 88017

Lepidopteran-and Rootworm-Protected Corn
(OECD Unique Identifier: MON-89034-3 x MON 88017-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.001-0.0024%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0030-0.0057%

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn.....0.0037-0.0070%

Inert Ingredient:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....0.0038-0.0069%

Percentage (wt/wt) on a dry weight basis whole plant (forage)

Caution

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS_____

EPA Registration No. 524-LTA

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

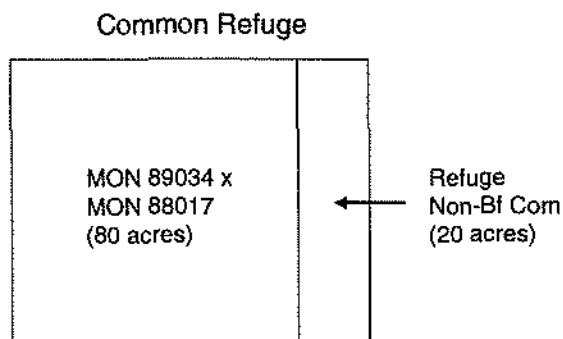
MON 89034 x MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 x MON 88017 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid sweet corn.

For MON 89034 x MON 88017 sweet corn, growers are required to destroy any MON 89034 x MON 88017 sweet corn stalks that remain in the field following harvest via rotary mowing, disking, or plow-down within one (1) month of harvest.

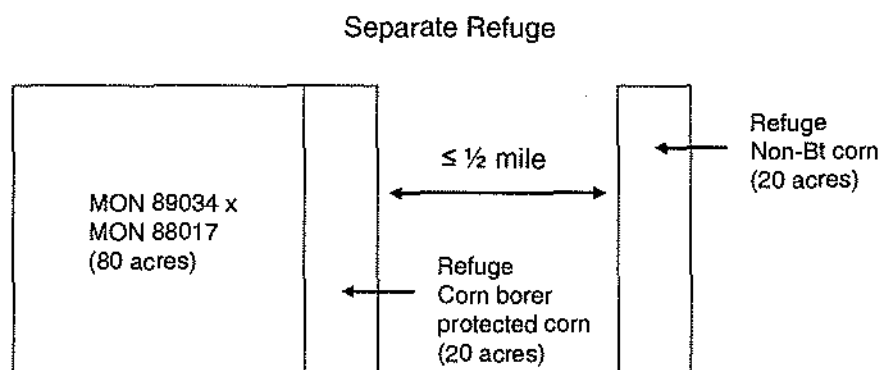
For MON 89034 x MON 88017 field corn, two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of MON 89034 x MON 88017 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted). It can be planted as block within or adjacent (e.g., across the road) to the MON 89034 x MON 88017 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for the control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field (acres) must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



The second option is planting separate refuge areas (e.g., two refuge areas, a double refuge, or paired refuge areas) for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 20% of the grower's corn acres, and must be planted within ½ mile of the MON 89034 x MON 88017 field. Refuge planting options include: separate fields, blocks within fields (e.g. along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 rows wide. The corn borer refuge can be treated with an insecticide for corn rootworm larval control, or a non-Bt foliar applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, but can be planted with Bt hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., corn rootworm refuge must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted) and can be planted as a block within or adjacent to the MON 89034 x MON 88017 field, strips around the field, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 rows wide. The corn rootworm refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if corn rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field must be treated in a similar manner. A schematic of one separate refuge option with the corn rootworm refuge planted as a block within the field and the corn borer refuge planted within a ½ mile of the MON 89034 x MON 88017 field is shown below:



Corn Insects Controlled

European corn borer
Southwestern corn borer
Southern cornstalk borer
Corn earworm
Fall armyworm
Corn stalk borer
Sugarcane borer

Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Diatraea saccharalis

Western corn rootworm
Northern corn rootworm
Mexican corn rootworm

Diabrotica virgifera virgifera
Diabrotica barberi
Diabrotica virgifera zeae

Sales of corn hybrids that contain Monsanto's Bt corn ~~plant pesticide~~ must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 x MON 88017 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUN 09 2008

MEMORANDUM

SUBJECT: Consideration of Section 3(c)(7)(C) Conditional Time-Limited Registration for Monsanto's Plant-incorporated Protectants, *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Insecticidal Protein and the Genetic Material Necessary for Their Production in MON 89034 Corn
(EPA File Symbols 524-LTA and 524-LTL) -DECISION MEMORANDUM

FROM: Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division

TO: Debra Edwards, Ph.D., Director
Office of Pesticide Programs

I. ISSUE

Should the Agency conditionally register the subject pesticides until September 30, 2010 pursuant to FIFRA §3(c)(7)(C)?

II. RATIONALE FOR RECOMMENDATION

Section 3(c)(7)(C) of FIFRA provides for the conditional registration of new active ingredients if it is determined that 1) use of the pesticide during a defined period of time will not cause any unreasonable adverse effect on the environment; 2) use of the pesticide is in the public interest; and 3) that for the data that is lacking, a reasonable period of time sufficient for generation of the data has not elapsed since the Agency first imposed the data requirements.

To satisfy criterion (1) above, we have determined that this plant-incorporated protectant pesticide will not cause any unreasonable adverse effects on human health or the environment.

The data have been reviewed and BPPD has determined that a section 3(c)(7)(C) conditional registration that is limited in duration is appropriate in this situation. Data requirements for granting the subject time-limited registrations for use of these products under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been met. BPPD has determined that these products will cause no unreasonable adverse effects to the environment if used in compliance with the terms and conditions of registration, as presented in the Biopesticide

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Registration Action Document (BRAD) for *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 insecticidal protein and the genetic material necessary for their production in MON 89034 corn.

III. RECOMMENDATION

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking if insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and the registration and use of the pesticide during the conditional registration is in the public interest. EPA determines that all of these criteria have been fulfilled.

Insufficient time has elapsed since the initial imposition of the data requirements for:

- 1) An independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105 to satisfy residue analytical method in plants requirements for event MON 89034 corn and event MON 89034 x MON 88017 corn.
- 2) A 7 to 14 day *Daphnia* study as per the 885 Series OPPTS Guidelines or, alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams.
- 3) Additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determination of how such cross-resistance may impact the durability of MON 89034.
- 4) Baseline susceptibility studies and/or a discriminating concentration assay that are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.
- 5) Baseline susceptibility studies to support sweet corn uses that must be conducted on FAW populations collected from sweet corn growing areas; monitoring studies that will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres; and monitoring of the collected populations of FAW for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.

The applicants submitted or cited data sufficient for EPA to determine that conditional registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment. The applicants submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and nontarget organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to Cry2Ab2 and Cry 1A.105 proteins, during the conditional registrations, is not expected to be significant.

Registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn is in the public interest because:

(1) Registration of MON 89034 is expected to result in the reduction of the use of higher risk, and often less effective and more expensive, conventional pesticides. A reduction in use of conventional pesticides equates to less potential for adverse effects to human health and the environment.

(2) Additionally, MON 89034 provide a wider spectrum of protection against primary and secondary corn pests, which should facilitate greater grain quality, a reduction of mycotoxin contamination, increased yield and ultimately, positive implications for human health.

In view of these minimal risks and the clear benefits related to *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn, EPA believes that the use of these products during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, EPA is imposing the data requirements specified in Section III of the BRAD.

EPA has determined, as explained in the Benefits and Public Interest Finding Assessment, that the use of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under these registrations are in the public interest.

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of these

registrations. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

The expiration date of the registrations has been set to September 30, 2010.

CONCUR: ✓

NON-CONCUR: _____

DATE: 6/9/08

Walter Edwards

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 09 2008

MEMORANDUM

SUBJECT: Consideration of Section 3(c)(7)(C) Conditional Time-Limited Registration for Monsanto's Plant-incorporated Protectants, *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Insecticidal Protein and the Genetic Material Necessary for Their Production in MON 89034 Corn
(EPA File Symbols 524-LTA and 524-LTL) -DECISION MEMORANDUM

FROM: Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division

TO: Debra Edwards, Ph.D., Director
Office of Pesticide Programs

I. ISSUE

Should the Agency conditionally register the subject pesticides until September 30, 2010 pursuant to FIFRA §3(c)(7)(C)?

II. RATIONALE FOR RECOMMENDATION

Section 3(c)(7)(C) of FIFRA provides for the conditional registration of new active ingredients if it is determined that 1) use of the pesticide during a defined period of time will not cause any unreasonable adverse effect on the environment; 2) use of the pesticide is in the public interest; and 3) that for the data that is lacking, a reasonable period of time sufficient for generation of the data has not elapsed since the Agency first imposed the data requirements.

To satisfy criterion (1) above, we have determined that this plant-incorporated protectant pesticide will not cause any unreasonable adverse effects on human health or the environment.

The data have been reviewed and BPPD has determined that a section 3(c)(7)(C) conditional registration that is limited in duration is appropriate in this situation. Data requirements for granting the subject time-limited registrations for use of these products under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been met. BPPD has determined that these products will cause no unreasonable adverse effects to the environment if used in compliance with the terms and conditions of registration, as presented in the Biopesticide

CONCURRENCES

SYMBOL	751P	751P						
SURNAME	Janet L. Andersen	Debra Edwards						
DATE	6/9/08	6/9/08						30

Registration Action Document (BRAD) for *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 insecticidal protein and the genetic material necessary for their production in MON 89034 corn.

III. RECOMMENDATION

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking if insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and the registration and use of the pesticide during the conditional registration is in the public interest. EPA determines that all of these criteria have been fulfilled.

Insufficient time has elapsed since the initial imposition of the data requirements for:

- 1) An independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105 to satisfy residue analytical method in plants requirements for event MON 89034 corn and event MON 89034 x MON 88017 corn.
- 2) A 7 to 14 day *Daphnia* study as per the 885 Series OPPTS Guidelines or, alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams.
- 3) Additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determination of how such cross-resistance may impact the durability of MON 89034.
- 4) Baseline susceptibility studies and/or a discriminating concentration assay that are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.
- 5) Baseline susceptibility studies to support sweet corn uses that must be conducted on FAW populations collected from sweet corn growing areas; monitoring studies that will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres; and monitoring of the collected populations of FAW for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.

registrations. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

The expiration date of the registrations has been set to September 30, 2010.

CONCUR: ✓

NON-CONCUR: _____

DATE: 6/9/08

Alma Schwandt

The applicants submitted or cited data sufficient for EPA to determine that conditional registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment. The applicants submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and nontarget organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to Cry2Ab2 and Cry 1A.105 proteins, during the conditional registrations, is not expected to be significant.

Registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn is in the public interest because:

(1) Registration of MON 89034 is expected to result in the reduction of the use of higher risk, and often less effective and more expensive, conventional pesticides. A reduction in use of conventional pesticides equates to less potential for adverse effects to human health and the environment.

(2) Additionally, MON 89034 provide a wider spectrum of protection against primary and secondary corn pests, which should facilitate greater grain quality, a reduction of mycotoxin contamination, increased yield and ultimately, positive implications for human health.

In view of these minimal risks and the clear benefits related to *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn, EPA believes that the use of these products during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, EPA is imposing the data requirements specified in Section III of the BRAD.

EPA has determined, as explained in the Benefits and Public Interest Finding Assessment, that the use of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under these registrations are in the public interest.

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of these

EPA Registration File No. 524-576 Vol. # 1.

Page _____ is not included in this copy.

Pages 34 through 49 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

 X FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-client communication.

_____ Claimed confidential by submitter upon submission to the Agency.

_____ Third party confidential business information.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



Sheryl
Reilly/DC/USEPA/US
05/22/2008 10:01 AM

To Alan Reynolds/DC/USEPA/US@EPA, Jeannette
Martinez/DC/USEPA/US@EPA, cerrelli.susanne@epa.gov
cc mendelsohn.mike@epa.gov

bcc

Subject Fw: Background info for today's Conference call regarding
proposed changes to IRM refuge plans

----- Forwarded by Sheryl Reilly/DC/USEPA/US on 05/22/2008 09:59 AM -----



"Lucy Reed"
<reedle@inspection.gc.ca>
05/21/2008 04:05 PM

To Sheryl Reilly/DC/USEPA/US@EPA
cc "Tanya Fielding" <fieldingt@inspection.gc.ca>
Subject Re: Conference call regarding proposed changes to IRM
refuge plans

Hi Sheryl,

Actually here's a bit of background for you and your group to
consider for tomorrow's call.

In Canada, a condition of authorization for the unconfined
environmental release of Bt corn is the implementation of an insect
resistance management (IRM) plan; this condition is imposed to
manage an identified risk. In Canada, there is one "generic" plan
for corn resistant to the European Corn Borer (ECB) and one
"generic" plan for those crops resistant to corn rootworm (CRW). A
main component of both of these plans is the requirement for a 20%
refuge to be planted.

Results from the 2007 Stratus Canadian phone survey regarding
compliance with IRM plan requirements has indicated that compliance
with the 20% refuge requirement has decreased relative to the 2005
and 2003 phone surveys. As a result, the Canadian Food Inspection
Agency (CFIA) is planning to host a one day meeting in September
2008 with relevant companies/industry members to discuss how the
industry intends to increase the rate of compliance with this IRM
plan requirement.

Against that backdrop of decreasing compliance, two companies have
approached the CFIA with IRM plans with alternative refuge
requirements. The CFIA does not dispute that IRM plans with
different refuge requirements could be scientifically valid, but if
they are not applied correctly, the validity of this science is
lost. Part of the risk management process in Canada includes CFIA
confidence that all conditions for the management of risk will be
met by the proponent. The CFIA is concerned that authorizing the
environmental release of Bt corn products with IRM plans with
various refuge requirements, whether it be size or even layout, will
create a complicating factor in growers' compliance with IRM
requirements at large (i.e., that compliance will decrease even
further), even more so if growers buy seed from 2 or 3 different
companies. For example, a producer might plant a 5% refuge for a
hybrid that requires a 20% refuge. Alternatively, if they buy seed

from 2-3 companies, they may opt to apply the simplest IRM plan of all three products across the board.

Currently, industry has not been able to maintain compliance with the current "generic" plans; therefore, there is concern that industry will not be able to ensure the proper application/implementation of IRM plans with varying refuge requirements (i.e., that an IRM plan will be correctly applied to the authorized product, and only to the authorized product). Prior to moving forward, CFIA regulators must not only have internal discussions, but also discussions with industry and other relevant stakeholders on how industry will ensure that the requirements for different IRM plans will be met on an ongoing basis. The CFIA plans to discuss this at the September 2008 meeting as well.

The purpose of Thursday's conference call is to discuss whether the EPA has similar concerns and internal discussions as the CFIA. Furthermore, the CFIA would like to involve the EPA in its discussions with industry at the September 2008 meeting.

I hope this helps to fill in the gaps a bit, and we look forward to talking to you tomorrow.

Kind regards,

Lucy

Tanya Fielding

Lucy Reed, M.Sc.

(613) 221-4704 | reedle@inspection.gc.ca | Facsimile / Télécopieur :

(613) 228-6140

Plant Biosafety Management Specialist, Canadian Food Inspection Agency

Spécialiste, gestion de la biosécurité végétale, Agence canadienne d'inspection des aliments

59 Camelot Drive | 59, promenade Camelot Ottawa ON K1A 0Y9

Government of Canada | Gouvernement du Canada

www.inspection.gc.ca

*IRM compliance inspection every 2 yrs
of grower's field by CFIA volunteers*

*Canadian
corn pest
control is
- group / cons. having
they conduct.*

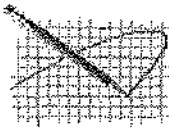
*phone survey to see if complying w/
In Canada, can make part of education
to time limited authorization for them*

*Cons. plans have
discussion w/ group of pig group of companies*

*For US company has the OARS
of determining rate of compliance.*

*"CAP" meets in US
for group (CBST)*

*Grower Education is big part of this (51)
Does PBMS - review grower education program
→ No (every) physically says
renewal that not*



Mike
Mendelsohn/DC/USEPA
/US

05/22/2008 03:14 AM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc John Kough/DC/USEPA/US@EPA

bcc

Subject Fw: Latest version for EPA

Susanne,

FYI- This is an example of what Monsanto sent a few years ago to address the microbial data waivers. The eco section of the BRAD does address at least some waivers. I don't know if or how Monsanto submitted them.

Sorry about not getting the tolerance exemption piece - just not enough time. John probably has it taken care of already. My thought was to explain how most of the tox and allergenicity data was not developed based on the plant produced protein, but on the bacterially produced protein and on the sequence that was in the vector for the AA homology. On the analytical method, I thought we could say we have a method, but it was not needed because this is a tolerance exemption. Also on the glycosylation section, I thought adding basic information relative to the eucaryotic nature of glycosylation might help and that the Cry protein is a procaryotic protein.

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
<http://www.epa.gov/pesticides/biopesticides>

----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 05/22/2008 03:05 AM -----

Mike
Mendelsohn/DC/USEPA
/US

05/19/2008 07:51 AM

To Mike Mendelsohn/DC/USEPA/US@EPA

cc

Subject Fw: Latest version for EPA

----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 05/19/2008 07:45 AM -----



"SCHNEIDER,
RUSSELL P [AG/1920]"
<russell.p.schneider@monsanto.com>

02/21/2003 09:04 AM

To Mike Mendelsohn/DC/USEPA/US@EPA, Phil
Hutton/DC/USEPA/US@EPA

cc

Subject FW: Latest version for EPA

Mike/Phil,

MONSANTO



MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005-7211
PHONE (202) 783-2460
FAX (202) 789-1819
<http://www.monsanto.com>

May 7, 2008

Dr. Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
United States Environmental Protection Agency
Washington, DC 20460

Subject: Pre-Acceptance Letter for MON 89034 and MON 89034 x MON 88017
EPA Petition Numbers: 6F7142 and 6F7143
EPA File Symbols: 524-LTA, 524-LTL
Application Date: September 29, 2006

Dear Dr. Reilly:

This is a response of Monsanto Company to the above stated pre-acceptance letter dated May 6, 2008 from EPA with respect to Section 3 registrations of Monsanto's Bt corn MON 89034 (Cry1A.105 and Cry2Ab2) and MON 89034 x MON 88017 (Cry1A.105, Cry2Ab2, Cry3Bb1) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Monsanto Company accepts all the proposed conditions for registration with the following modification:

- 1) **Page 2: the table**, row 3, column 2, Monsanto will conduct a 7 to 14 day Daphnia study as per the 885 Series OPPTS Guidelines. The reason for changing 21 day to 7-14 day study is that the 21 day guideline was designed for testing microbial pesticides. For Bt proteins, the pathogenicity and infectivity is not an issue. The 2000 EPA-SAP and 2007 EPA white paper (ed, Robyn Rose) recommended to conduct a minimum 5 day, preferably 7-14 days daphnia study for Bt proteins.
- 2) **Page 4: section a**, 4th paragraph, last line, change "Monsanto PIP products" to "Monsanto corn PIP products." **Page 6: section v**, lines 8 and 10, change "PIP products" to "Monsanto corn PIP products." **Page 10**, last line of 2nd paragraph, change "Monsanto PIP products" to "Monsanto corn PIP products".

Similarly on **Page 12, section v**, lines 7 and 10, change "PIP products" to "Monsanto corn PIP products."

In addition, we suggest the following editorial changes/correction:


- i. **Page 9: point vi**, change "April 30th" to "August 31st" to be consistent with point iv of Page 8. Also, on page 9, **section a)** Refuge Requirements for MON 89034 x MON 88017, third paragraph, change "MON 89034" to "MON 89034 x MON 88017".
- ii. **Page 15: first paragraph of section e)**, correct typing error of "889034" to "89034". Also, on page 15, **point vi**, change "April 30th" to "August 31st" to be consistent with point iv of Page 8.

Per your request in the pre-acceptance letter, the following administrative materials are also provided herein:

- a) Updated labels for MON 89034 and MON 89034 x MON 88017
- b) Updated Confidential Statement of Formula (CSF)
- c) Updated Certification with Respect to Citation of Data Form
- d) Updated data matrix of MON 89034 and MON 89034 x MON 88017

If you have any questions regarding this letter and the attached materials please feel free to contact Dr. Russell Schneider, Senior Director, Monsanto Regulatory Affairs & Policy at (202) 383-2866, or me at the phone numbers or e-mail listed below.

Sincerely



Yong Gao, Ph.D.
Regulatory Affairs Manager
Monsanto Company

Office: (314) 694-2943
Mobile: (314) 488-0971
yong.gao@monsanto.com

cc: Susanne Cerrelli, EPA/OPP/BPPD
Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto
Carolyn Carrera, Monsanto

MONSANTO



MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005-7211
PHONE (202) 783-2460
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<http://www.monsanto.com>

May 7, 2008

Dr. Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
United States Environmental Protection Agency
Washington, DC 20460

Subject: Pre-Acceptance Letter for MON 89034 and MON 89034 x MON 88017
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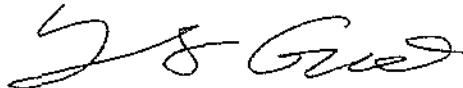
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Sincerely



Yong Gao, Ph.D.
Regulatory Affairs Manager
Monsanto Company

Office: (314) 694-2943
Mobile: (314) 488-0971
yong.gao@monsanto.com

cc: Susanne Cerrelli, EPA/OPP/BPPD
Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto
Carolyn Carrera, Monsanto

Plant-Incorporated Protectant Label

MON 89034 x MON 88017

Lepidopteran-and Rootworm-Protected Corn
(OECD Unique Identifier: MON-89034-3 x MON 88017-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.001-0.0024%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0030-0.0057%

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn.....0.0037-0.0070%

Inert Ingredient:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....0.0038-0.0069%

Percentage (wt/wt) on a dry weight basis whole plant (forage)

Caution

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-LTA

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

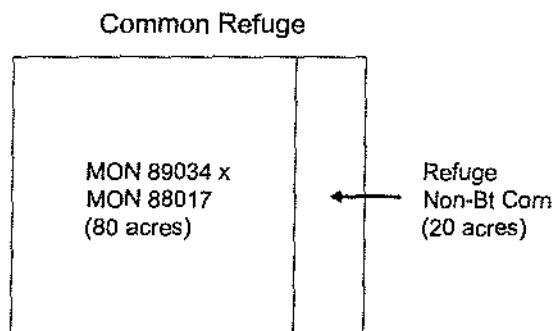
MON 89034 x MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 x MON 88017 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid sweet corn.

For MON 89034 x MON 88017 sweet corn, growers are required to destroy any MON 89034 x MON 88017 sweet corn stalks that remain in the field following harvest via rotary mowing, disking, or plow-down within one (1) month of harvest.

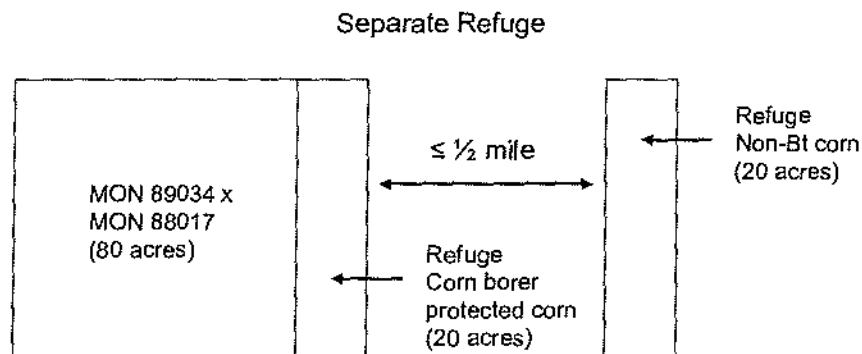
For MON 89034 x MON 88017 field corn, two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of MON 89034 x MON 88017 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted). It can be planted as block within or adjacent (e.g., across the road) to the MON 89034 x MON 88017 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. The common refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for the control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field (acres) must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



The second option is planting separate refuge areas (e.g., two refuge areas, a double refuge, or paired refuge areas) for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 20% of the grower's corn acres, and must be planted within ½ mile of the MON 89034 x MON 88017 field. The corn borer refuge can be treated with an insecticide for corn rootworm larval control, or a non-Bt foliar applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, but can be planted with Bt hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., corn rootworm refuge must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted) and can be planted as a block within or adjacent to the MON 89034 x MON 88017 field, strips around the field, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. The corn rootworm refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if corn rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field must be treated in a similar manner. A schematic of one separate refuge option with the corn rootworm refuge planted as a block within the field and the corn borer refuge planted within a ½ mile of the MON 89034 x MON 88017 field is shown below:



Corn Insects Controlled

European corn borer	<i>Ostrinia nubilalis</i>
Southwestern corn borer	<i>Diatraea grandiosella</i>
Southern cornstalk borer	<i>Diatraea crambidoides</i>
Corn earworm	<i>Helicoverpa zea</i>
Fall armyworm	<i>Spodoptera frugiperda</i>
Corn stalk borer	<i>Papaipema nebris</i>
Sugarcane borer	<i>Diatraea saccharalis</i>
Western corn rootworm	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm	<i>Diabrotica barberi</i>
Mexican corn rootworm	<i>Diabrotica virgifera zeae</i>

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 x MON 88017 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Registration File No. 524-576 Vol. # 1.

Page _____ is not included in this copy.

Pages 61 through 64 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

X The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-client communication.

_____ Claimed confidential by submitter upon submission to the Agency.

_____ Third party confidential business information.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167
(314) 694-2943

EPA Registration Number / File Symbol:

524-LTA

Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vector PV-ZMIR245 and Vector PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Date:

May 7, 2008

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:

Terrestrial field crop

Product Name:

MON 89034 x MON 88017

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐

I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒

I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature



Date

May 7, 2008

Typed or Printed Name and Title

Yong Gao, Ph.D.
Regulatory Affairs Manager

EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: May 7, 2008

EPA Reg. No./File Symbol: 524-LTA

Page 1 of 29

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2500	Hartmann, A.J., K.E. Niemeyer, and A. Silvaovich. 2006. Assessment of the CryIA.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-Protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL0020479.	469513-03	Monsanto Company	OWN	Product Characterization
885.2100	MacRae, T.C., C.R. Brown, and S.L. Levine. Evaluation of Potential for Interactions Between the <i>Bacillus thuringiensis</i> Proteins CryIA.105, Cry2Ab2, and Cry3Bb1. Monsanto Technical Report MSL-20270.	469513-05	Monsanto Company	OWN	Product Characterization
885.1100	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI.	N/A	Monsanto Company	OWN	Product Characterization
	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2 and Cry3Bb1 Proteins Produced in Insect-protected Corn MON 89034 x MON 88017. Monsanto Technical Report MSL-20434.	469513-01	Monsanto Company	OWN	Product Characterization
885.2100	Groat, J.R., B.J. Wolff, J.F. Rice, and J.D. Masucci. 2006. Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis. Monsanto Technical Report MSL-20145.	469513-02	Monsanto Company	OWN	Product Characterization

Signature

Name and Title
Yong Gao, PhD.
Regulatory Affairs Manager

Date
May 7, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Supplemental Information for "Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	Monsanto Company	OWN	Product Characterization
885.110	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.	469514-01	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.R. Groat, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Company	OWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Nicmeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Company	OWN	Product Characterization
885.1100	Karunanandaa, K., I.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E. coli-Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.	469514-04	Monsanto Company	OWN	Product Characterization
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in <i>E. Coli</i> and <i>Bt</i> Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	469514-05	Monsanto Company	OWN	Product Characterization
860.1340	Brown, M. (2003). <i>TraitChek™</i> Cry3Bb Lateral Flow Test Strip and <i>SeedChek™</i> Cry3Bb ELISA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategies Diagnostics, Inc.	463942-01	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran Species" (MRID No. 461817-04)	465783-03	Monsanto Company	OWN	Product Characterization
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the CryIA.105 Protein to CryIA Class of <i>Bacillus thuringiensis</i> Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y., B-P. Tonnu and R. P. Lirette (2001). Cry3Bb1, CryIAb and NPTII Protein Levels in the Dual-trait Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. Monsanto Technical Report MSL-17266.	457917-02	Monsanto Company	OWN	Product Characterization
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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167
Product: MON 89034 x MON 88017
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masucci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068.	466945-01	Monsanto Company	OWN	Product Characterization
885.1100	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Produced in MON 88017. Monsanto Technical Report, MSL-18835.	461817-01	Monsanto Company	OWN	Product Characterization
885.1100	Beasley, K. A., H.M. Anderson, P.B. Wimberley, D.W. Mittank, and R.P. Lirette. 2002. Molecular analysis of YieldGard® Rootworm/Roundup Ready® corn event MON 88017. Monsanto Technical Report, MSL-17609.	461817-02	Monsanto Company	OWN	Product Characterization
885.1100	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS protein levels in corn tissues collected from MON 88017 corn produced in U.S. field trials conducted in 2002. Monsanto Technical Report, MSL-18823.	461817-03	Monsanto Company	OWN	Product Characterization
885.110	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of functional equivalence of two Cry3Bb1 protein variants against susceptible Coleopteran species. Monsanto Technical Report, MSL-18799.	461817-04	Monsanto Company	OWN	Product Characterization

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Dudin, Y. A., B-P. Tonnu, L. D. Allee and R. P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. Monsanto Technical Report, MSL-17181.	454240-01	Monsanto Company	OWN	Product Characterization
885.1100	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MON 863. Monsanto Technical Report, MSL-17137.	454240-10	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of <i>B.t.</i> Protein 11098, <i>B.t.</i> Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources. Technical Report MSL-17222.	454240-04	Monsanto Company	OWN	Product Characterization
885.2100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the CryIA.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and <i>E.coli</i> -Produced CryIA.105 Proteins. Monsanto Technical Report, MSL-19960.	466946-04	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Corn Event MON 863 to Microbial Sources. Technical Report MSL-17220.	454240-05	Monsanto Company	OWN	Product Characterization
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.100	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by <i>E. coli</i> Fermentation and MON 863. Monsanto Technical Report, MSL-17274.	455382-01	Monsanto Company	OWN	Product Characterization
860-1340	Kobwyck, D., B-P. Tonn, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Monsanto Company	OWN	Product Characterization
885.100	Thoma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1. 11098 Protein Using N-terminal Sequencing and MALDI Time of Flight	454240-11	Monsanto Company	OWN	Product Characterization
885.1100	Bogdanova, N. (2007). Supplemental Information for MRID No. 46951302 "Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis".	471275-02	Monsanto Company	OWN	Product Characterization
885.1100	Bogdanova, N. (2007). Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034".	471275-03	Monsanto Company	OWN	Product Characterization
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	N. Bogdanova (2007). Supplemental Information for MRID No. 46951303 "Assessment of the CryIA.105, Cry2Ab2, Cry3Bb1 and CP4EPSPS Protein levels in Selected Tissues of Insect-Protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials".	471275-04	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the CryIA.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Company	OWN	Product Characterization
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the <i>in vitro</i> Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	469514-07	Monsanto Company	OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the CryIA.105 Protein Utilizing the AD6, TOXINS, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	469514-10	Monsanto Company	OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXINS, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-11	Monsanto Company	OWN	Human Health Assessment
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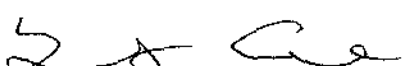
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto study number 05-01-50-13, Amended report.	469514-12	Monsanto Company	OWN	Human Health Assessment
885.1100	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. Monsanto Technical Report MSL-17223.	454240-07	Monsanto Company	OWN	Human Health Assessment
885.11	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of B.t. Protein 11098 and B.t. Protein 11231 Sequences Utilizing Toxin and Public Domain Genetic Databases. Technical Report MSL-15870.	449043-08	Monsanto Company	OWN	Human Health Assessment
885.11	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of B.t. Protein 11098 and B.t. Protein 11231 Sequences Utilizing an Allergen Database. Technical Report MSL-15873.	449043-09	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the <i>In Vitro</i> Digestibility of B.t. protein 11098 and B.t. 11231 Utilizing Mammalian Digestive Fate Models. Technical Report MSL-17166.	454240-06	Monsanto Company	OWN	Human Health Assessment
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938.	469514-09	Monsanto Company	OWN	Human Health Assessment
885.30	Bechtel, C. L. (1999). Acute Oral toxicity of B.t. Protein 11098 in Mice. Monsanto Technical Report MSL-16215.	449043-06	Monsanto Company	OWN	Human Health Assessment
885.30	Bechtel, C. L. (1999). Acute Oral Toxicity of B.t. Protein 11231 in Mice. Monsanto Technical Report MSL-16216.	449043-05	Monsanto Company	OWN	Human Health Assessment
885.11	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the CryIA.105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the CryIA.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Company	OWN	Human Health Assessment
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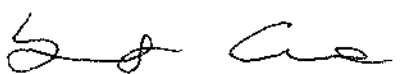
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with CryIA.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Company	OWN	Human Health Assessment
885.3050	Kapadia, S. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the CryIA.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Company	OWN	Human Health Assessment
885.3050	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and CryIA.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report, MSL-19899.	466946-07	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. Monsanto Technical Report, MSL-17530.	455770-02	Monsanto Company	OWN	Human Health Assessment
885.11	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. Monsanto Technical Report, MSL-17140.	454240-08	Monsanto Company	OWN	Human Health Assessment
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Ingredient: <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3050	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> Produced Cry3Bb1.t1098(Q349R) Protein. Amended Final Report. Monsanto Technical Report, MSL-17382.	455382-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from <i>E. coli</i> . Monsanto Technical Report, MSL-17292.	455382-03	Monsanto Company	OWN	Human Health Assessment
N/A	Astwood, J. D., R. E. Hileman, M. J. McKee, T. J. Rydel, J. W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. Monsanto Technical Report, MSL-17225.	454240-09	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto study CRO-2005-049.	469514-06	Monsanto Company	OWN	Human Health Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> Cry2Ab2 Protein. Monsanto Technical Report MSL-20229.	469514-14	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient: Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto	469514-15	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (<i>Folsomia candida</i>). Monsanto Technical Report MSL-20169.	469514-16	Monsanto Company	OWN	Environmental Assessment
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.	469514-27	Monsanto Company	OWN	Environmental Assessment
885.5200	Mueth, M., T. Curran, J. Warco, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and CryIA.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Company	OWN	Environmental Assessment
N/A	Huesing, J.E., J.F. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Company	OWN	Environmental Assessment
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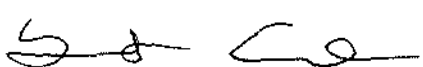
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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167
EPA Reg. No./File Symbol: 524-LTA Page 13 of 29
Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran <i>Daphnia magna</i> : An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.	469514-17	Monsanto Company	OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to CryIA.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.	469514-18	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a CryIA.105 Protein on Honeybee Larvae (<i>Apis mellifera</i> L.). Monsanto study CA-2005-071.	469514-19	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a CryIA.105 Protein on Adult Honeybees (<i>Apis mellifera</i> L.). Monsanto study CA-2005-072.	469514-20	Monsanto Company	OWN	Environmental Assessment
885.4380	Levine, S. (2006). An Evaluation of Insect Bioefficacy of Combination Trait Products Produced Through Conventional Breeding MON 89034 x NK603 and MON 89034 x MON 88017: MSL-20336	469513-04	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of CryIA.105 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.	469514-21	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V.L. 2000. Evaluation of the Effect(s) of Purified Bacillus thuringiensis Cry2Ab2 Protein on Honey Bee Larvae. Monsanto Technical Report MSL-16961.	453371-02	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (<i>Apis mellifera</i> L.). Study CA-99-058, Monsanto Technical Report, MSL-16176.	450863-08	Monsanto Company	OWN	Environmental Assessment
860-1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Company	OWN	Environmental Assessment
885.4340	MacRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the Bacillus Thuringiensis Proteins Cry1A.105 and Cry2Ab2. Monsanto Technical Report, MSL-19859.	466946-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S.J. and H.O. Kreuger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report, MSL-16177.	450863-13	Monsanto Company	OWN	Environmental Assessment
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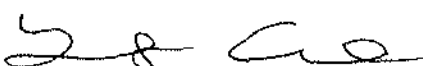
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthrenidae). Monsanto Technical Report MSL-20170.	469514-23	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthrenidae). Monsanto Technical Report MSL-20171.	469514-24	Monsanto Company	OWN	Environmental Assessment
885.4340	Sinderman, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.	469514-25	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient: *Bacillus thuringiensis* CryI A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMR245 and PV-ZMR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V. L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees (<i>Apis mellifera</i> L.). Monsanto Technical Report MSL-16169.	449043-11	Monsanto Company	OWN	Environmental Assessment
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Aerobic Soil Degradation of the <i>B.t.</i> Protein 11098 as a Component of Insect Protected Corn. Monsanto Technical Report MSL-16440.	451568-04	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected MON 863. Monsanto Technical Report MSL-17102.	457571-02	Monsanto Company	OWN	Environmental Assessment
885.4050	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. Monsanto Technical Report MSL-17243.	459415-01	Monsanto Company	OWN	Environmental Assessment
885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999). <i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. Monsanto Technical Report, MSL-16161.	449043-15	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). Monsanto Technical Report, MSL-16166.	449043-14	Monsanto Company	OWN	Environmental Assessment
850-6200	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. Monsanto Technical Report, MSL-16162.	449043-16	Monsanto Company	OWN	Environmental Assessment
885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. Monsanto Technical Report, MSL-16164.	449043-19	Monsanto Company	OWN	Environmental Assessment
885.4200	McKee, M. J. (2001). Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. Monsanto Technical Report, MSL-17383.	455382-00	Monsanto Company	OWN	Environmental Assessment
885.4240 Series 72, Subdivision E	Drottler, K. R. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). Monsanto Technical Report, MSL-16163.	449043-18	Monsanto Company	OWN	Environmental Assessment
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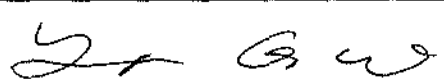
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 x MON 88017		
Ingredient Bacillus thuringiensis CryIA.I05, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. Monsanto Technical Report MSL-16168.	449043-10	Monsanto Company	OWN	Environmental Assessment
N/A	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. Monsanto Technical Report MSL-17614.	455770-03	Monsanto Company	OWN	Environmental Assessment
154-2300	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7.	456530-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., J. D. Duan, C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report, Monsanto Technical Report MSL-17531.	457916-01	Monsanto Company	OWN	Environmental Assessment
885.6200	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-18137.	457571-01	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address:

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Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein 11098 to Colletotrichum (<i>Folsomia candida</i>). Monsanto Technical Report, MSL-15988.	449043-17	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). Monsanto Technical Report, MSL-16165.	449043-12	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with the Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). Monsanto Technical Report, MSL-16167.	449043-13	Monsanto Company	OWN	Environmental Assessment
885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Report. Monsanto Ref. No. 99-894E.	453484-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . Monsanto Technical Report, MSL-16936.	453613-01	Monsanto Company	OWN	Environmental Assessment
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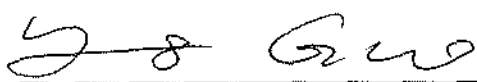
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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

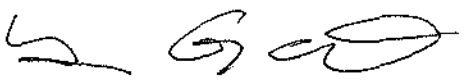
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (<i>Folsomia candida</i>). Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	OWN	Environmental Assessment
885.4280	Results of acute toxicity tests with <i>Daphnia</i> and catfish did not produce any evidence of adverse effects. Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Teixeira, D. (2005). Evaluation of Dietary Effects of a Cry3Bb1 Protein Variant on Minute Pirate Bugs (<i>Orius insidiosus</i>). MSL-19697	464799-05	Monsanto Company	OWN	Environmental Assessment
885.4300	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.5200	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-19285	465103-01	Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title Yong Gao, PhD. Regulatory Affairs Manager	Date May 7, 2008	



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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 x MON 88017		
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Bryan, R. L., J. R. Porch and H. O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, <i>Hippodamia convergens</i> . MSL-17171.	453613-02	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179.	455382-06	Monsanto Company	OWN	Environmental Assessment
885.4340	Dnan, J. J., M. J. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> .	455382-04	Monsanto Company	OWN	Environmental Assessment
885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (<i>Danux plexippus</i>) via Laboratory Bioassay. MSL-17235.	455382-05	Monsanto Company	OWN	Environmental Assessment
N/A	Head, G., M. Pleau, S. Sivansubramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein <i>in vitro</i> . C3NTO.	455382-07	Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title Yong Gao, PhD. Regulatory Affairs Manager		Date May 7, 2008




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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-3500	Duan J. J., C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Corn Event MON 863. MSL-19246	462627-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Nickson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Corn Event MON 863. MSL-19329	463942-02	Monsanto Company	OWN	Environmental Assessment
885-5200	Dubelman S., M. Bhatti and B. Ayden (2004). Interim Report: Assessment of the Environmental Fate of the Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-18931	462001-01	Monsanto Company	OWN	Environmental Assessment
885-4340	Duan J. and M. Paradise (2005). Evaluation of Dietary Effects of Cry3Bb1 Protein on the Ground Beetle <i>Poecilus chalcites</i> (Coleoptera:Carabidae). MSL-19631	464799-04	Monsanto Company	OWN	Environmental Assessment
154-3500	Head, G. (2004). Research on the Effects of Corn Rootworm Protected Transgenic Corn on Non-Target Organisms: Publications & Manuscripts	462627-02	Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title Yong Gao, PhD. Regulatory Affairs Manager		Date May 7, 2008

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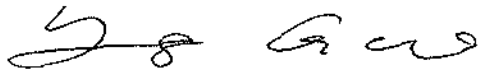
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Data Waiver Request: Toxicity of <i>B.t.</i> Cry3Bb1 Protein in the Red Milkweed Beetle (<i>Tetraopes</i> sp.). Monsanto Technical Report MSL-18741.	N/A	Monsanto Company	OWN	Environmental Assessment Granted in BRAD
885.4150	Mammalian wildlife exposure to Cry3Bb1 protein is considered likely; however, the Cry3Bb1 toxicity data for Human Health Assessment indicate that there is no significant toxicity to rodents from testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> CryIA.105 Protein. Monsanto Technical Report MSL-20230.	469514-13	Monsanto Company	OWN	Environmental Assessment
N/A	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E.	450297-01	Monsanto Company	OWN	Benefits
N/A	Vaughn, T. T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (<i>Diabrotica barberi</i>), Southern Corn Rootworm (<i>D. undecimpunctata howardi</i>), and Western Corn Rootworm (<i>D. virgifera virgifera</i>). MTC RPT4.	455382-08	Monsanto Company	OWN	Benefits
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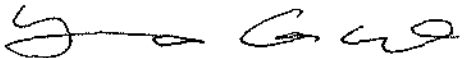
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 x MON 88017		
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Pitcher, C. D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3.	453613-03	Monsanto Company	OWN	Benefits
N/A	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in MON 863. Monsanto Technical Report MSL-17766.	456530-01	Monsanto Company	OWN	Benefits
N/A	Mitchell, P. D. (2002). Yield Benefit of MON 863. Monsanto Technical Report MSL-17782.	456530-02	Monsanto Company	OWN	Benefits
N/A	Alston, J. M., f. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - Yield [®] Rootworm. MSL-17993.	456923-01	Monsanto Company	OWN	Benefits
	Bogdanova, N., A. Crawford (2007). Public Interest Document Supporting Registration of <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017		Monsanto Company	OWN	Benefits
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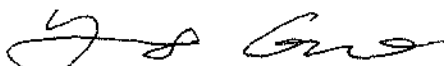
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Control Product. Monsanto Technical Report	455770-01	Monsanto Company	OWN	Benefits/IRM
N/A	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4.	459438-01	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	IRM
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2004). Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	Monsanto Company	OWN	IRM
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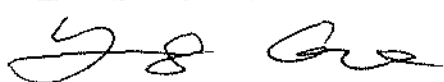
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 x MON 88017		
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. and K. Reding. (2006). Corn rootworm Insect Resistance Management Research (fourteen journal publications)	467424-01	Monsanto Company	OWN	IRM
N/A	T. Vaughn (2004). Progress Report on Insect Resistance Management for Corn Event MON 863.	461865-01	Monsanto Company	OWN	IRM
N/A	T. Vaughn (2005). Second Progress Report on Insect Resistance Management for Corn Event MON 863. REVISED	N/A	Monsanto Company	OWN	IRM
N/A	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the corn rootworm pest complex.	N/A	Monsanto Company	OWN	IRM
	Head, G.P. Insect Resistance Management Plan for the Combined Trait Product MON 89034 x MON 88017. Monsanto Technical Report 06-RA-39-06.	469513-06	Monsanto Company	OWN	IRM
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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Petition for Exemption from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	Monsanto Company	OWN	Tolerance Exemption
N/A	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant <i>Bacillus thuringiensis</i> Corn Rootworm Control Protein, as Produced in the Corn (<i>Zea mays</i> , L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	Monsanto Company	OWN	Tolerance Exemption
N/A	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	451568-00	Monsanto Company	OWN	Tolerance Exemption
885.3050	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223.	436433-03	Monsanto Company	OWN	Inert Ingredient
885.1100	Ream, J., M. Bailey, J. Leach and S. Padgett (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949.	436433-04	Monsanto Company	OWN	Inert Ingredient
Signature 			Name and Title Yong Gao, PhD. Regulatory Affairs Manager	Date May 7, 2008	

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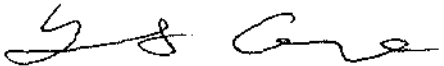
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient: <i>Bacillus thuringiensis</i> CrytA.105, Cry2Ab2, and Cry3Bbt Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRIQ Number	Submitter	Status	Note
885.3050	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgett (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12: 92-419-	436919-01	Monsanto Company	OWN	Inert Ingredient
885.1100	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. Padgett (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30/14: 12901.	436433-01	Monsanto Company	OWN	Inert Ingredient
885.1100	Padgett, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-Enolpyruvylshikimate-3-phosphate Synthase from <i>Agrobacterium</i> sp. Strain CP4. Monsanto Technical Report MSL-12738.	438076-01	Monsanto Company	OWN	Inert Ingredient
885.1100	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant <i>Escherichia coli</i> Fermentation. Monsanto Technical Report MSL-12389.	438076-02	Monsanto Company	OWN	Inert Ingredient
885.1100	Hecreo, R., S. Padgett and M. Gustafson (1993). The Purification of Recombinant <i>Escherichia coli</i> CP4 5-enolpyruvylshikimate-3-phosphate synthase for Equivalence Studies. Monsanto Technical Report MSL-12574.	438076-03	Monsanto Company	OWN	Inert Ingredient
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in <i>Escherichia coli</i> and European Corn Borer Resistant Corn. Lab Project Number: 94-01-39-10; Monsanto Technical Report MSL-13920.	436433-02	Monsanto Company	OWN	Inert Ingredient
	Bogdanova, N. (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTA and 524-LTA to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Company	OWN	Misc.
	Bogdanova, N. (2007). Responses to EPA Questions Regarding Applications 524-LTA and 524-LTA to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	471275-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., Dubelman, S., Much, M., Murphy, J. And Silvanovich, A. (2007). Responses to EPA Questions Regarding Application 524-LTA to Register Insect-protected Corn MON 89034 (MRID 46951428)		Monsanto Company	OWN	Misc.
Signature 			Name and Title Yong Gao, PhD. Regulatory Affairs Manager		Date May 7, 2008



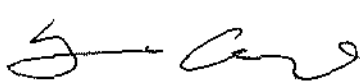
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DATA MATRIX

Date: May 7, 2008		EPA Reg. No./File Symbol: 524-LTA		Page 1 of 29	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
Signature 		Name and Title Yong Gao, PhD. Regulatory Affairs Manager		Date May 7, 2008	

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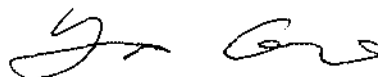
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DATA MATRIX

Date: May 7, 2008 EPA Reg. No./File Symbol: 524-LTA Page 2 of 29

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.t05, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Signature			Name and Title Yong Gao, PhD. Regulatory Affairs Manager	Date May 7, 2008	

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Date: May 7, 2008	EPA Reg. No./File Symbol: 524-LTA	Page 3 of 29
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017		

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Date: May 7, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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Date: May 7, 2008 EPA Reg. No./File Symbol: 524-LTA Page 5 of 29

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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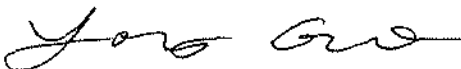
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
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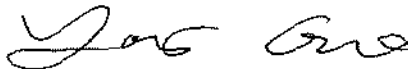
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
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			Monsanto Company	OWN	Human Health Assessment
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Date: May 7, 2008 EPA Reg. No./File Symbol: 524-LTA Page 9 of 29

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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Date: May 7, 2008	EPA Reg. No./File Symbol: 524-LTA	Page 10 of 25
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017
Ingredient: Bacillus thuringiensis CryIA. t05, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

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Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
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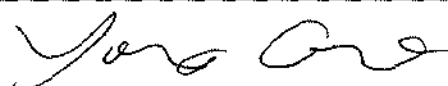
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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167
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Product: MON 89034 x MON 88017
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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Applicant's/Registrant's Name & Address:
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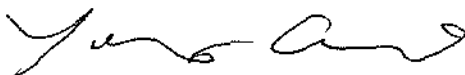
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DATA MATRIX

Date: May 7, 2008
Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167
EPA Reg. No./File Symbol: 524-LTA Page 17 of 29
Product: MON 89034 x MON 88017
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title Yong Gao, PhD. Regulatory Affairs Manager	Date May 7, 2008	

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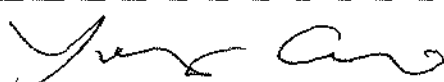
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			Monsanto Company	OWN	Environmental Assessment

Signature

Name and Title
Yong Gao, PhD.
Regulatory Affairs Manager

Date
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment Waived in BRAD
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment Waived in BRAD
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title Yong Gao, PhD. Regulatory Affairs Manager	Date May 7, 2008	

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Signature

Name and Title
Yong Gao, PhD.
Regulatory Affairs Manager

Date
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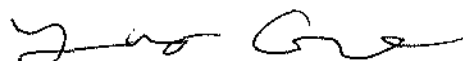
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			Monsanto Company	OWN	Environmental Assessment Granted in BRAD
			Monsanto Company	OWN	Environmental Assessment Waived in BRAD
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Benefits
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			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
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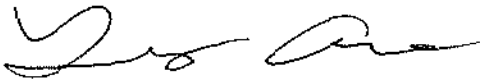
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Benefits/IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
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Signature			Name and Title		
			Yong Gao, PhD. Regulatory Affairs Manager		
			Date		
			May 7, 2008		

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			Monsanto Company	OWN	Tolerance Exemption
			Monsanto Company	OWN	Tolerance Exemption
			Monsanto Company	OWN	Tolerance Exemption
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
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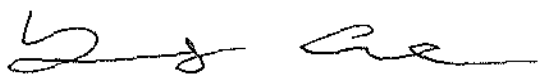
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			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
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			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Misc.
			Monsanto Company	OWN	Misc.
			Monsanto Company	OWN	Misc.
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			Monsanto Company	OWN	Misc.
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY - 6 2008

OPP Decision Numbers: D-371189
D-371190

Yong Gao
Regulatory Affairs Manager
Monsanto Company
1300 I Street, NW
Suite 450 East
Washington, DC 20005

Subject: Pre-Acceptance Letter for: MON 89034 (Cry1A.105 and Cry2Ab2) and
MON89034 x MON 88017 (Cry1A.105, Cry2Ab2 and Cry3Bb1) Corn

EPA Petition Numbers: 6F7142 and 6F7143

EPA File Symbols: 524-LTA, 524- LTL

Application Date: September 29, 2006

EPA Receipt Date: September 29, 2006

Dear Dr. Gao:

This is a pre-acceptance letter regarding Monsanto Company's applications to register the above referenced products for Section 3 registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider registering Monsanto Company's products under FIFRA Section 3(c)(7)(C) provided Monsanto Company amends its applications for registration by submitting the required information as described in this letter.

This letter does not constitute a commitment to register the subject product, nor is it intended to imply that EPA will register the subject product. Rather, the purpose of this letter is to inform you that, if Monsanto Company submits the information in writing as described in this letter, EPA will be able to continue to process the registration application in accordance with our normal procedures.

Thus, to enable us to continue to process the subject registration application, EPA requests that Monsanto Company agrees in writing to the following.

- 1) The subject registrations will automatically expire on midnight September 30, 2010.

- 2) The subject registrations will be continued to MON 89034 and MON 89034 x MON

SYMBOL	7511P	88017 in field or sweet corn. Further	MON 89034 and MON 89034 x MON					
SURNAME	Sherrill	7511P						
DATE	5-6-08	July						

88017 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 and MON 89034 x MON 88017 sweet corn may not be sold to small roadside or home growers

- 3) Submit/cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4) Submit the following data in the time frames listed:

Data Required to Support Both MON 89034 and MON 89034 x MON 88017

OPPTS Guideline/ Study Type	Required Data	Due Date
860.1340 Residue Analytical method - Plants	For event MON 89034 corn and event MON 89034 x MON 88017 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105. You must also agree to provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	4/1/2009
850.1010 Aquatic Invertebrate Acute Toxicity Testing, Freshwater <i>Daphnids</i>	A 21 day daphnia study, as outlined in the OPPTS Microbial Test Guidelines, needs to be performed for <u>MON 89034</u>	4/1/2009
Insect Resistance Management	Monsanto did not address the likelihood of cross-resistance of Cry1A.105, Cry1Ac, Cry tFa, proteins already in existing Bt corn and Bt cotton products, and what impact such cross-resistance would have on the durability of MON 89034. Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry tFa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It is important to address not only the likelihood of cross-resistance potential of Cry tA.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry tA.105 and Cry1Ac and Cry1Fa.	4/1/2009 Protocol Due 8/1/2008

Insect Resistance Management	Monsanto did not sufficiently address the cross-resistance of Cry1A.105, Cry1Fa, and Cry1Ac in the cotton-growing landscape and how cross-resistance may impact the durability of MON 89034. Should cross-resistance be of concern then the durability of MON 89034 in the southern cotton-growing areas might be compromised. Monsanto needs to address this issue in subsequent simulation modeling.	4/1/2009 Protocol Due 8/1/2008
Insect Resistance Management	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.	4/1/2009
Insect Resistance Management	To support sweet corn uses, baseline susceptibility studies must be conducted on FAW populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2010

Additional Data Required to Support MON 89034 and MON 89034 x MON 88017

5) Submit or cite all data required to support the individual plant-incorporated protectant in Event MON863 (YieldGard Rootworm), 524-528. In the event that the Agency concludes MON 863 (YieldGard Rootworm) studies do not sufficiently demonstrate a lack of significant adverse effects, additional data with MON 88017 corn must be submitted. This data may include a) laboratory toxicity testing with *Orius insidiosus* (minute pirate bug), b) laboratory toxicity testing with a carabid (ground beetle), c) long range effects testing on invertebrate populations in the field, and d) long range soil persistence testing.

6) Apply to amend the MON 88017 registration to allow the breeding use to produce MON 88017 x MON 89034.

7) You must commit to do the following Insect Resistance Management Program for MON 89034.

a) Refuge Requirements for MON 89034.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn nor to commercial hybrid sweet corn.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements or, in the case of sweet corn, harvest practices as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of [MON 89034] acres and corn borer refuge acres), and must be planted within ½ mile of the [MON 89034] field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Growers who fail to comply with the IRM requirements risk losing access to Monsanto PIP products.

b) Grower Agreements for MON 89034.

- i. Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- ii. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- iii. The registrant must integrate this registration into the current system used for their other Bt corn PIPS to reasonably likely to assure that persons purchasing the Bt corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description must be submitted to EPA by August 1, 2008.
- iv. The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a

proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

- v. The registrant must integrate this registration into the current system to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system. A description must be submitted to EPA by August 1, 2008.
- vi. The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- vii. Beginning on January 31, 2010 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON 89034 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve month period covering the prior August through July.
- viii. The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Programs for MON 89034.

- i. Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON 89034 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 89034 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 89034 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON 89034 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
- ii. Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph vi. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

- iii. On January 31, 2010, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs iv.-xv.) below.
- iv. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 89034 Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON 89034 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other Bt corn PIPS. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program. Other required features of the program are described in paragraphs v. – xv.) below.
- v. The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of noncompliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the Monsanto PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto PIP products.
- vi. The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S. The survey will include only growers planting at least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.
- vii. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

- viii. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- ix. The registrant shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.
- x. Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs vi. through viii. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.
- xi. The registrant shall train its representatives who make on-farm visits with MON89034 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance. This on-farm assessment program has no minimum acreage threshold for growers.
- xii. The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- xiii. If a grower, who purchases MON 89034 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- xiv. Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- xv. The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the

State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d) Insect Resistance Monitoring for MON 89034.

The Agency is imposing the following conditions for this product:

- i. Post-commercial resistance monitoring programs must be established as an extension of existing programs to track the susceptibility of the key lepidopteran corn pests to the Cry1A.105 and Cry2Ab2 proteins. For the Cry1A.105 and Cry2Ab2 proteins, the registrant will monitor for resistance and/or trends in increased tolerance for European corn borer, Southwestern corn borer, and corn earworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. Monitoring must be carried out under the same protocols used for the products containing MON 810. Sampling should be focused in those areas in which there is the highest risk of resistance development. In the monitoring program, insect populations will be collected and each protein will be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.
- ii. In addition to monitoring ECB, SWCB, and CEW, Monsanto will develop and ensure the implementation for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. The registrant should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which MON 89034/ MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.
- iii. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- iv. The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2010, reporting on populations collected the previous year.

e) Remedial Action Plans for MON 89034

The October 15, 2001 Remedial Action Plan for Responding to Resistance in European Corn Borer, Corn Earworm and/or Southwestern Corn Borer must be used for suspected and confirmed resistance of these pests.

The annual reporting requirements are as follows:

- i. Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- ii. Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- iii. Grower Education: substantive changes to education program completed previous year, January 31st each year;
- iv. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- v. Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- vi. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, April 30th each year.

8) You must commit to do the following Insect Resistance Management Program for MON 89034 x MON 88017.

a) Refuge Requirements for MON 89034 x MON 88017

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn nor to commercial hybrid sweet corn.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements or, in the case of sweet corn, harvest practices as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

For MON 89034 x MON 88017 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, disking, or plow-down within one (1) month of harvest.

Two options for deployment of the refuge are available to growers. The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and refuge acres). It can be planted as a block adjacent to the [MON 88017 x MON 89034] field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4, and preferably 6

consecutive rows wide. If strips within the [MON 88017 x MON 89034] field are implemented, then at least 4, and preferably 6 consecutive rows should be planted. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 89034] field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and corn borer refuge acres), and must be planted within ½ mile of the [MON 88017 x MON 89034] field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. The corn rootworm refuge must be planted with a non-Bt/corn rootworm-protected hybrid, but can be planted with Bt corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and corn rootworm refuge acres) and can be planted as an adjacent block, perimeter strips, or in-field strips. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 89034] field must be treated in a similar manner. Growers who fail to comply with the IRM requirements risk losing access to Monsanto PIP products.

b) Grower Agreements for MON 89034 x MON 88017

- i. Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- ii. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- iii. The registrant must integrate this registration into the current system used for their other Bt corn PIPS to reasonably likely to assure that persons purchasing the Bt corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description must be submitted to EPA by August 1, 2008.

- iv. The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.
- v. The registrant must integrate this registration into the current system to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system. A description must be submitted to EPA by August 1, 2008.
- vi. The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- vii. Beginning on January 31, 2010 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON 89034 x MON 88017 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve month period covering the prior August through July.
- viii. The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Programs for MON 89034 x MON 88017

- i. Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON 89034 x MON 88017 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 89034 x MON 88017 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 89034 x MON 88017 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON 89034 x MON 88017 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

- ii. Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph vi. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- iii. On January 31, 2010, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs iv.-xv. below.
- iv. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 89034 x MON 88017 Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON 89034 x MON 88017 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other Bt corn PIPS. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program. Other required features of the program are described in paragraphs v. – xv. below.
- v. The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of noncompliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of Monsanto PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto PIP products
- vi. The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S. The survey will include only growers planting at

least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.

- vii. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- viii. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- ix. The registrant shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.
- x. Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.
- xi. The registrant shall train its representatives who make on-farm visits with MON89034 x MON 88017 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance. This on-farm assessment program has no minimum acreage threshold for growers.
- xii. The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- xiii. If a grower, who purchases MON 89034 x MON 88017 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- xiv. Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints,

grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.

- xv. The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d) Insect Resistance Monitoring for MON 89034 x MON 88017

The Agency is imposing the following conditions for this product:

- i. Post-commercial resistance monitoring programs must be established as an extension of existing programs to track the susceptibility of the key lepidopteran corn pests to the Cry1A.105 and Cry2Ab2 proteins. For the Cry1A.105 and Cry2Ab2 proteins, the registrant will monitor for resistance and/or trends in increased tolerance for European corn borer, Southwestern corn borer, and corn earworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. Monitoring must be carried out under the same protocols used for the products containing MON 810. Sampling should be focused in those areas in which there is the highest risk of resistance development. In the monitoring program, insect populations will be collected and each protein will be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.
- ii. In addition to monitoring ECB, SWCB, and CEW, Monsanto will develop and ensure the implementation for resistance monitoring for *Spodoptera frugiperda* (fall armyworm of FAW) in counties which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. The registrant should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which MON 89034/ MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.
- iii. For the Cry3Bb1 portion of the product, a revised Cry3Bb1 monitoring plan that incorporates MON 89034 x MON 88017 must be submitted to the Agency within 90 days of the date of registration.
- iv. For the Cry3Bb1 portion of the product, the registrant must develop and validate an appropriate discriminating or diagnostic dose assay by January 31, 2010.

- v. For the Cry3Bb1 portion of the product, the registrant must finalize rootworm damage guidelines and submit these to BPPD by January 31, 2010.
- vi. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- vii. The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2010, reporting on populations collected the previous year.

e) Remedial Action Plans for MON 89034 x MON 88017

The October 15, 2001 Remedial Action Plan for Responding to Resistance in European Corn Borer, Corn Earworm and/or Southwestern Corn Borer must be used for suspected and confirmed resistance of these pests. The current remedial action plan approved for MON 863 must be used for corn rootworm suspected and confirmed resistance in [MON 89034 x MON 88017]. If corn rootworm resistance is confirmed, all acres ([MON 89034 x MON 88017] and refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

The annual reporting requirements are as follows:

- i. Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- ii. Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- iii. Grower Education: substantive changes to education program completed previous year, January 31st each year;
- iv. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- v. Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- vi. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, April 30th each year.

9) Label and Administrative Materials:

You must submit an updated label, Confidential Statement of Formula (CSF), Certification with Respect to Citation of Data form, and data matrix for both products. The labels must list separately those pests that are controlled and those that are suppressed as well as the IRM refuge and harvest requirements. The data matrix and Certification with Respect to Citation

of Data form should have the same date. Each of the CSFs and labels should have the same product name and be based on actual expression level data. You must also formally address all the requirements listed in 40 CFR Part 158.740, e.g. via waiver requests where appropriate. The updated label should include modifications to the IRM requirements listed in this letter.

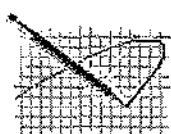
This letter does not mean that EPA agrees to amend the subject product. If Monsanto Company submits the information in writing as described in this letter, however, EPA will be able to continue to process the registration application.

Please contact Susanne Cerrelli of my staff at (703) 308-8077 should you have any questions or wish to schedule a meeting.

Sincerely,



Sheryl K. Reilly, Ph.D. Chief
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)



Mike
Mendelsohn/DC/USEPA
/US

04/22/2008 10: t9 PM

To Zigfridas Vaituzis/DC/USEPA/US@EPA

cc Alan Reynolds/DC/USEPA/US@EPA, Annabel
Waggoner/DC/USEPA/US@EPA, Susanne
Cerrelli/DC/USEPA/US@EPA, Sheryl

bcc

Subject MON 89034 Eco Review

Zig,

My understanding of the the information we need follows. I will be out tomorrow but should be in the office for our briefing of Janet on Thursday.

Best Regards,

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
<http://www.epa.gov/pesticides/biopesticides>

Background

MON 89034 contains Cry1A.105 and Cry2Ab2
MON 88017 contains Cry3Bb1

MON 89034 nontarget terrestrial invertebrate studies are limited to either Cry1A.105 or Cry2Ab2 studies except for Collembola where leaf tissue containing both proteins was tested.

Cry1A.105 is a chimeric protein created by Monsanto with domains from three Cry proteins; Cry1Ab, Cry1Ac, and Cry1F.

For the pending MON 89034 and MON 89034 x MON 88017 registrations, we have received the following nontarget organism assessments: (1) 12/14/2007 MON 89034 review of non-target invertebrate studies on Cry1A.105 and Cry2Ab2, (2) 12/14/2007 MON 89034 review of broiler, quail, soil fate, and endangered species, (3) 12/14/2007 MON 89034 x MON 88017 review regarding potential interactions between Cry1A.105, Cry2Ab2, and Cry3Bb1, and (4) a MON 89034 and MON 89034 x MON 88017 Environmental Assessment BRAD chapter that is unsigned and undated.

Since 2001, we have been requiring long term field studies for PIP soil degradation and non-target invertebrate impacts. Much of this data has been received and is awaiting final review. This data needs to be reviewed prior to November 2008 when we extend the registrations of ECB active Bt corn. Of these, the Cry1Ab long term soil fate data has been reviewed and we determined no further testing is necessary for Cry1Ab. I believe Cry1Ac soil fate has also been reviewed.

Several of us in MPB, including yourself, have exchanged emails and subsequently met on April 1st regarding regarding stacked/pyramid PIPs and additive vs. synergistic effects. In a 3/28 email you mentioned that "[w]e are going to get more and more of them involving more

than 3 proteins, so the simple synergy/additive effect testing may no longer give us the information we want." During the April 1st meeting you further indicated that in some cases bridging data using target insect species may not be adequate and we may need to test representative nontarget organisms with the protein combinations.

Requests

1) Provide a signed version of the environmental assessment. In the past, this has been done by the eco team by providing a signature block and date at the beginning of the BRAD chapter.

2) Provide more explanation in the BRAD/ environmental assessment as to why the long term non-target invertebrate impacts studies are not being required. Specifically, provide more of a description of the Marvier et. al. and Sanvido et. al. studies cited.

Currently the BRAD chapter states:

The Agency expects that Tier 1 testing for short-term hazard assessment will be sufficient for most studies submitted in support of PIP registrations. However, if long range adverse effects must be ascertained, then higher-tier longer-term field testing will be required. As noted above, the October 2000 SAP and the National Academy of Sciences 1 (NAS 2000) recommended testing non-target organisms directly in the field. This approach, with an emphasis on testing invertebrates found in corn fields, was also recommended by the August 2002 SAP and was supported by several public comments. Recent analyses of short term and long term field study effects on invertebrate populations in Bt corn and cotton fields indicate that no unreasonable adverse effects are taking place as a result of wide scale Bt crop cultivation.² Slight reductions in some invertebrate predator populations are an inevitable result of all pest management practices which result in reductions in the abundance of the pests as prey. Based on these considerations, regulatory testing of the specialist predators and parasitoids of target pests may eventually be considered unnecessary.

1 (*Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* is available from the National Academy Press, 2101 Constitution Avenue, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); <http://www.nap.edu> .

2 Marvier, M., McCreedy, C., Regetz, J. & Kareiva, P. A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates. *Science* 316, 1475-1477 (2007). Sanvido, O., Romeis, J., Bigler, F. (2007). Ecological Impacts of Genetically Modified Crops: Ten Years of Field Research and Commercial Cultivation. *Adv Biochem Eng/Biotechnol* 107: 235-278

3) Provide more explanation in the BRAD/ environmental assessment as to why the long term soil degradation studies are not being required. The Cry1Ab study reviewed by Tessa and cited in the BRAD chapter has been reviewed. However, Cry1F, Cry3Bb1 x Cry1Ab, and several other long term soil degradation studies are pending final review. Please further explain the underlying basis for "no detectable Cry protein accumulation in agricultural soils."

Currently the BRAD chapter states:

...More specifically, a study that evaluated Cry1Ab protein accumulation in a field with three years of continuous Cry1Ab field corn production showed that the protein had not accumulated in soil to a level that would elicit a toxic response from ECB larvae, a species that is highly susceptible to Cry1Ab protein (Milofsky, 2006).

No additional soil degradation studies are required for Cry2Ab2 or Cry1A.105 proteins. As a result of FIFRA Scientific Advisory Panel recommendations and public comments, the Agency has been receiving three year soil fate studies for the currently registered Cry protein producing crops grown in a variety of soils and environmental conditions. The results show that there is no detectable Cry protein accumulation in agricultural soils during commercial planting of currently registered Cry protein producing crops.

4) Update p.7 of the BRAD chapter regarding protein interaction in accord with the 12/14/2007 review. The cited 7/6/06 Hunter review states "The study report is classified as supplemental. The study is upgradeable to "acceptable" when test replication and insect numbers are reported. In addition, this study is classified as unacceptable for Section 3 registration."

5) Confirm that the 12/14/2007 potential interaction review agrees with your current position of potential protein interactions in light of discussions and emails in MPB regarding stacked/pyramid PIPs and additive vs. synergistic effects. Specifically, confirm that no additional non-target data on the stacks of the proteins are necessary.

Zigfridas Vaituzis/DC/USEPA/US



Zigfridas
Vaituzis/DC/USEP
A/US

04/12/2008 12:16
AM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc Alan Reynolds/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Annabel
Waggoner/DC/USEPA/US@EPA

Subject A PS to our last meeting...

Susanne:

I apologize for my unfriendly attitude at the meeting on the MON89034 x MON88017 PIP the other day. I was overwhelmed with shock after all the work that we put into that BRAD chapter. And it was one of the best ones that we had come up with until Annabel did the VipCot. I could not help but overreact when all I perceived at the meeting was uninformed picky criticism. I guess that I have not yet gotten used to that even after all these years.. [and I keep on telling Annabel to get used to it already!]. It is my goal to get used to it before I retire. If I keep on reacting as I did the other day, I will have to hang around for too many more years in order to learn... or leave as a failure..)-:

Unfortunately, my response did not give opportunity for you to express all that you need. What is it you need?

From some of the comments I heard I surmise you would like a Memo summarizing the Eco risk assessment. But the introduction summary and the conclusion at the end of the document have the information that would go into a Memo. A memo was not prepared because the memos were written when all that the RALs received was the DERs and a Memo. With that the RALs had to write the BRAD chapter. Because now the science staff is preparing the chapter for the BRAD, a summary Memo is unnecessary. Or is it? Could be that you need one for the Fact Sheet? - let me know what it is you want. But I still maintain that the BRAD chapter has all of the necessary information and all one has to do is block and paste from the summary and conclusion sections... into a fact sheet.

As for the Memo that Mike wants saying that we no longer require long term soil studies and field testing - that was said in the BRAD for this product with the published literature as justification. Peer reviewed published literature summarizing one hundred field tests over 10 years of use carries much more credibility than one of two studies by a registrant. And not

asking for these studies needs to remain as a 'waiver' on a case-by-case basis. We can waive it for the well-known Bt proteins that have been on the market for years. The data may become again necessary for the next product that comes in the door. A signed 'policy' memo waiving the requirement would pick up a life of its own and would be used by registrants to argue that we ceased that requirement for good. It is not our intent to cease field and soil testing for all future PIPs. [A written policy memo would have to clearly define where we draw the line - and who knows where to draw the line when we have no idea what the industry is coming up with next?]

So now that I am over the 'shock' - let me know if you still need something from us, within reason... In general I recommend that if there are issues that are not clear to you - as long as the registration is not being held up - take the word of the science team and get on with it.. that is why we are the scientists. The RALs are not expected to do or critique science [except where the scientists ignore the OPP SOPs and FIFRA requirements].

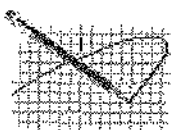
Don't let my poor attitude keep you from asking for the information that you need to get your job done. My poor attitude is my problem, not yours.

Peace!

[zig.v]

Zig Vaituzis, Ph.D., Team Leader
Environmental Risk Assessment Team
Biopesticides and Pollution Prevention Division
USEPA (7511P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460.0001
Tel: 703-308-8676
Fx: 703-308-7026
vaituzis.zigfridas@epa.gov

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Susanne
Cerrelli/DC/USEPA/US
04/14/2008 11:38 AM

To Mike Mendelsohn/DC/USEPA/US@EPA
cc
bcc

Subject Fw: A PS to our last meeting...- Please comment and CC me

Mike-

My understanding is that we want the following from Zig/ Annabel Eco team:

Annabel has an understanding of what we need which includes:

- (1) A memo or DER - for the "Peer reviewed published literature summarizing one hundred field tests over 10 years" that we can use for these registrations and others that are pending or come in the future.
- (2) Clarification in writing preferably about the need for additional non-target insect testing on actual foliage from the two new registrations MON 89034 and MON89034 x 88017. Only one insect was tested with foliage with the Bt proteins incorporated.
- (3) A memo or DER that expresses in writing why we are accepting the synergy information, and that explains in more detail what published literature we are relying upon.
- (4) The eco-chapter that had been prepared earlier with clarifications mentioned above about cited literature, any additional confirmatory data needed and a signature page.

Mike- This is just from my memory, I am sure I missed something, please comment.

Thanks for all your help on this!!!

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

-----Forwarded by Susanne Cerrelli/DC/USEPA/US on 04/14/2008 11:23AM -----

To: Susanne Cerrelli/DC/USEPA/US@EPA
From: Zigfridas Vaituzis/DC/USEPA/US
Date: 04/12/2008 12:16AM
cc: Alan Reynolds/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Annabel Waggoner/DC/USEPA/US@EPA
Subject: A PS to our last meeting...

Susanne:

I apologize for my unfriendly attitude at the meeting on the MON89034 x MON88017 PIP the other day. I was overwhelmed with shock after all the work that we put into that BRAD chapter. And it was one of the best ones that we had come up with until Annabel did the VipCot. I could not help but overreact when all I perceived at the meeting was uninformed picky criticism. I guess that I have not yet gotten used to that even after all these

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Alan
Reynolds/DC/USEPA/U
S
04/08/2008 12:45 PM

To Susanne Cerrelli/DC/USEPA/US@EPA
cc
bcc
Subject Re: Fw: Edits and Additions to MON 89034 and MON 89034
x MON 88017 - What about sweet corn IRM??

Hi Susanne-

The sweet corn part is OK....Monsanto's response was acceptable and they don't need to provide any more data.

The terms and conditions for sweet corn should mimic those for other Bt sweet corn registrations (i.e. Syngenta's Attribute sweet corn). I think we have some language regarding crop destruction in lieu of a refuge. Mike should be able to help find the language....if not, I can help you tomorrow.

Alan

Susanne Cerrelli/DC/USEPA/US



Susanne
Cerrelli/DC/USEPA/US
04/08/2008 10:24 AM

To Alan Reynolds/DC/USEPA/US@EPA
cc
Subject Fw: Edits and Additions to MON 89034 and MON 89034 x
MON 88017 - What about sweet corn IRM??

Alan-

I am getting pressure from Monsanto and Mike to wrap up the PA letter. Please let me know if you have comments today. Mike was asking me about sweet corn, and your review

of MON 89034 states: BPPD agrees that no structured refuge is needed in conjunction with the sweet corn use based on the destruction of potential resistant larvae through cultivation practices.

Can you confirm that we don't need anything more for sweet corn? Sharlene had asked for data and expression and activity last year for sweet corn. Was Monsanto's response totally ok for sweet corn IRM??

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

----- Forwarded by Susanne Cerrelli/DC/USEPA/US on 04/08/2008 09:56 AM -----



Annabel
Waggoner/DC/USEPA/US
02/17/2008 06:00 PM

To Zigfridas Vaituzis/DC/USEPA/US@EPA

cc

bcc

Subject Additive vs. Synergistic effects

History:

✉ This message has been replied to and forwarded.

Hi Zig,

Here's is some info' of **Additive vs. Synergistic** effects that I pulled from Alan Raybould's paper. I also attached the paper for you as well. Hopefully, it's the right one...

"The most powerful test of the hypothesis that the hazard is not greater than additive (not synergistic) is to examine the effects of the mixture in species that are sensitive to at least one of the proteins; If a species sensitive to both proteins is available, dose response curves for the separate proteins would be obtained. The predicted response of the species to mixtures of the proteins can be obtained from these data.

The predicted effect depends upon the modes of action of the proteins. If the proteins have different modes of action, the predicted effect of the mixture should be calculated using a model called **independent joint action**. Under this model, if a certain amount of protein A alone kills x% of a sample, and a certain amount of protein B kills y%, the predicted percentage kill of a mixture of these amounts of protein is given by $x + y - (xy/100)$ Colby (1967) If protein A kills x%, protein B will kill y% of the remainder, i.e. $x + y/100(100-x) = x + y - xy/100$. The observed and expected mortalities are compared over a range of concentrations. There is no test of statistical significance; the predicted dose response curves are compared with the expected dose response curves and if there is greater mortality than expected over the range of concentrations the hypothesis of synergism is falsified. If the studies corroborate the hypothesis of no synergism in sensitive pest species, it is likely that there will be no synergism of the mixture against non-target organisms, and that the risk hypothesis of $HQ < 1$ for all non-target organisms exposed to the mixture is corroborated. No testing of the mixture against non-target organisms should be necessary under these circumstances."



Raybould.Eco.GM.crops.risk.assessment.2007.pdf

Annabel Waggoner, Environmental Protection Specialist
U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
Microbial Pesticide Branch
(703) 308-0340
waggoner.annabel@epamail.epa.gov

Mailing Address:
OPP/ Biopesticides and Pollution Prevention Division Mailcode: 7511P
U.S. EPA
1200 Pennsylvania Avenue NW
Washington DC 20460

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Briefing for MON 89034 + X

Blog =

- (A) All the conditions of request for another product are ongoing in } left active BT corn

Issues

Soil fall

Not target used

(B) Smart Stack-

(C) Synergism Bridging decisions

(1) zig → add signature block
or memo

(2) ~~Do~~ If persist
In light of data coming up w/ Oct
+ that previously
meta analysis supersedes zig reviews

Es
drafts
on page 5

anticipate reviews done

Issue's
suggested
text to
insert

"We have frequently required this data over the past --- 10 yrs"

This paper --- (describe findings)

The Agency agrees to the conclusions of this paper

7

Issue 3 Soil degradation

→ 10 yr study can support soil degradation

→ Could add citation explanation

c → sentence that states EPA agrees position in the paper
Storing papers Support

Amabel's General Summary mentioned in ^{OED 10 yr.} ~~WAS~~
publication 'Consensus doc ... July 2007

Issue 4 page 7 → ^{Note} suggests citing the
"Further data was submitted to support Section 3 registration"
or something

Issue
suggested
inserting

Issue 5 → IAH Synergy + Data req?

VIPCO7 synergy an
showed //

Superstack → -

Do we want more data?

don't need more no-forgoir inxels
for Pms MON89034 * X



Mike
Mendelsohn/DC/USEPA
/US

04/04/2008 12:48 AM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc

bcc

Subject Edits and Additions to MON 89034 and MON 89034 x MON
88017
PA Letter

History:

 This message has been forwarded.

Susanne,

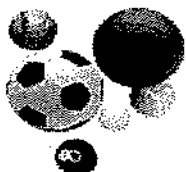
Thanks for sending the initial draft. I made some edits and additions. I combined the 2 PA letters into one, used the PA letter format, and tried to use track changes. We need to check with Alan re: sweet corn requirements and monitoring for fall armyworm. The edited letter is attached FYI. I have also provided a link to the 2001 reassessment. You can find sweet corn requirements there under the IRM section,
http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad.htm.

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (75 t1P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
<http://www.epa.gov/pesticides/biopesticides>



4 PA 4 3 2008.doc

150



DeVenchi
Arnold/DC/USEPA/US
02/13/2008 10:04 AM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc

bcc

Subject FOIA Request RIN-0616-08

Hey Susanne, the DERs that I need are for MRID numbers 469513-04, -05, -06, 469514-13, -14 and -30. I have check Reg.gov and noticed that the studies are listed on there so releasing these DERs will not be a problem. Thanks a lot for any help you can provide with getting these. If there are any questions please feel free to contact me.

DeVenchi P. Arnold
Information Management Specialist
OPP/ITRMD/PIRIB (7502-P)
U.S. Environmental Protection Agency
Washington, D.C. 20460
(703)305-5698
Fax: 703-305-5480

Visit OPP's new FOIA Website: <http://www.epa.gov/pesticides/foia/>



"SCHNEIDER,
RUSSELL P [AG/1920]"
<russell.p.schneider@m
onsanto.com>

01/23/2008 01:13 PM

To: Susanne Cerrelli/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA

cc

bcc

Subject: Slides for EPA on MON 89034

History: This message has been forwarded.

Please see attached the slides we used for our recent meeting. Also, based on our conversation, please accept this letter as Monsanto's desire to accept the registration of MON 89034 with a 20% refuge in all corn growing areas. We are excited to move this product along, and look forward to the pre-acceptance letter as soon as the Public Interest Document review is completed.

Please let me know if you need further clarification.

Russ

<<MON-EPA meeting Jan 10-2008.pdf>>

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transmitted by or accompanying this e-mail or any attachment. MON-EPA meeting Jan 10-2008.pdf

EPA Registration File No. 524-576 Vol. # 1.

Page _____ is not included in this copy.

Pages 153 through 157 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.
- ☐ Internal deliberative information.
- ☐ Attorney-client communication.
- ☒ Claimed confidential by submitter upon submission to the Agency.
- ☐ Third party confidential business information.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

1-10-08

Meeting with Monsanto @ MON 89034x MON 88017

<u>attendees</u>		<u>phone #</u>
Sherry Rolly (by phone)		703-308-8269
Alan Reynolds	BPPD	703-605-0515
Annabel Waggoner	BPPD	703-308-0340
Zig Vartuzis	BPPD	703-308-8676
Rebecca Edelstein	BPPD	703-605-0513
JOHN KOUGH	BPPD	703-308-8267
Suzanne Cervell	BPPD	703-308-8072
Philip Eppard	MON	314-694-5499
Graham Head	MON	314-694-7311
Russ Schneider	MONSANTO	202/383-2866
Michael Muelbach	BPPD	703-308-8715

Meeky/Monsanto

10-08

Dr Geo - ray spec. of Monsanto

asking @ ^{was} 7 day dose for Daphnia
instead of 2 days

Mon argues that AEI for microbes

b) difficult to conduct
in/poll ^{with fish}
(not stable) depends

7 day of it needed

• caveat

Caddisflies in literature on issue

as a tissue
seem to effect
caddisflies in
water

Further work may result additional req.
or removal of concern,

data req'd

IRM

IRM requested provide detail rationale
and details to support cross resistance questions

colony

binding studies

where can be used

Math modelling

Converging of dose
if

20% \rightarrow aimed to 5%

would have to extend PK/PD data

\Rightarrow bridging data can't support population

Alan indicated proposal
for addressing FRM OK

Monitors seeing earlier registration
- date of March

We indicated we can't commit
to that but can make it a goal

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 19 2007

OPP Decision Numbers: D-371189
D-371190

Yong Gao
Regulatory Affairs Manager
Monsanto Company
1300 I Street, NW
Suite 450 East
Washington, DC 20005

Dear Dr.Gao:

Subject: **MON89034 x MON 88017 (Cry1A.105, Cry2Ab2 and Cry3Bb1) Corn and MON89034 (Cry1A.105, and Cry2Ab2) Corn**
EPA Petition Numbers: 6F7142 and 6F7143
EPA File Symbols: 524-LTA and 524-LTL
Application Date: September 29, 2006
EPA Receipt Date: September 29, 2006

Your applications as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for this action category (B81 twice) by June 10, 2008.

Our review of your public interest document is ongoing. Provided that we are able to determine the registration of these products would be in the public interest, that you make the following changes to your proposed insect resistance management (IRM) refuges, and that you drop the proposed popcorn use, the Agency will be able to continue processing your applications.

If you choose not to modify the IRM refuge proposals and drop the popcorn use, the applications will be deemed incomplete. Within seventy-five (75) days, please indicate whether you will modify the IRM refuges and drop the popcorn use, and submit in writing a commitment to perform the required data listed below.

The Agency is requesting the following revisions to your proposed IRM refuges. Please consult the enclosed data evaluation records for detailed information.

CONCURRENCES							
SYMBOL	7511C	7511P	7511P	7511P			
SURNAME	Madh...	Reynolds	Stam...	Rull			1601
DATE	12/14/07	12/18/07	12/18/07	12/19/07			

REVISED IRM REFUGES

MON 89034 field corn uses in the corn belt including the separate refuge for 89034 x 88017.

(1) Pyramids can reduce the need for large refuges. Monsanto has proposed that a 5% structured refuge, rather than the current 20% structured refuge, be used with the field corn uses of MON 89034. However, Monsanto's data and modeling do not support a 5% structured refuge for MON 89034 for field corn uses in the Corn Belt. A 20% structured refuge requirement for field corn uses of MON 89034 in the Corn Belt can be supported at the present time.

(2) MON 89034 field corn use in cotton-growing areas. A 20% non-Bt corn refuge for MON 89034 in the southern cotton-growing areas would be sufficient to manage the risk of resistance evolution to Bt corn and Bt cotton products assuming there is no cross-resistance. Refer to sections (3) and (4) below.

The following data deficiencies must be addressed post-registration to support a conditional registration with the above mentioned revised 20% non-Bt IRM refuges and no popcorn use sites.

DATA REQUIRED POST-REGISTRATION WITH REVISED IRM REFUGES

(1) For event MON 89034 corn and event MON 89034 x MON 88017 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105 is needed.

(2) Freshwater aquatic invertebrates for MON 89034 (MRID 469514-17)

The *Daphnia magna* study is unacceptable because the 48 hour test duration is not sufficient to show mortality for Bt toxins. It takes more than 48 hours for the target pests to succumb to the Cry proteins therefore 48 hours is also too short to show mortality to *Daphnia*. A 21 day daphnia study, as outlined in the OPPTS Microbial Test Guidelines, needs to be performed. The study may be submitted as a condition of registration.

(3) Monsanto did not address the likelihood of cross-resistance of Cry1A.105, Cry1Ac, Cry1Fa, proteins already in existing Bt corn and Bt cotton products, and what impact such cross-resistance would have on the durability of MON 89034. Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.105 and Cry1Ac and Cry1Fa.

(4) Monsanto did not sufficiently address the cross-resistance of Cry1A.105, Cry1Fa, and Cry1Ac in the cotton-growing landscape and how cross-resistance may impact the durability of MON 89034. Should cross-resistance be of concern then the durability of

MON 89034 in the southern cotton-growing areas might be compromised. Monsanto needs to address this issue in subsequent simulation modeling.

(5) Monsanto is reminded that to support the sweet corn use site, a grower guide must be distributed to all customers using seed containing the plan-incorporated protectant that will include instructions and recommendations regarding product use, insect resistance management and integrated pest management. The following information regarding commercial productions must be included in the Grower guide:

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
- The allowed crop destruction methods are rotary mowing, disking, or plow-down. Crop-destruction methods should destroy any surviving resistant insects.

If Monsanto chooses to register their products with a 5% structured refuge the following additional data are required.

DATA REQUIRED TO SUPPORT MON 89034 FIELD CORN USES IN THE CORN BELT WITH A 5% STRUCTURED REFUGE:

Monsanto must address the uncertainties in the dose determination for ECB, SWCB, CEW, FAW (SS and RS mortality), cross-resistance likelihood of Cry tA. t05, Cry1Ac, and Cry1Fa and its impact on the durability of MON 89034, and limitations of the simulation modeling. Please also refer to the enclosed review for a full discussion of BPPD's analysis of the IRM plan for MON 89034.

a) **Dose determination.** Monsanto relies on the Roush (1998) model to support the need for a 5% structured refuge rather than a 20% structured refuge in the Corn Belt. Roush's model (1998; Figure 2) indicates that a 5% structured refuge is equal to or greater than a 20% structured refuge for a highly effective, high dose single-gene product when a two-gene product (MON 89034 in this case) achieves at least 95% control of susceptible homozygotes and 70% control of heterozygotes assuming there is no cross-resistance. The dose information provided by Monsanto is not sufficient to demonstrate that each protein will kill 95% of the homozygous susceptible insects and 70% of the heterozygotes. BPPD recommends that Monsanto further investigate whether MON 89034 consistently has high mortality of susceptible homozygotes (>95%) and whether the heterozygote mortality is at least 70% for MON 89034 against the target pests (for the Corn Belt – ECB and SWCB). The 1998 SAP suggested several ways to estimate mortality for less susceptible larvae (i.e. heterozygotes) (EPA 1998). These techniques included testing larger, later instar larvae that may be less susceptible.

b) **Cross Resistance.** Additional information is needed on cross-resistance of Cry tA.105 and Cry tFa and Cry1Ac (including binding site models and use of resistant colonies) for the target pests and a determination of how such cross-resistance may impact the durability of MON 89034. The Cry tA.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry tFa. It

is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.105 and Cry1Ac and Cry1Fa.

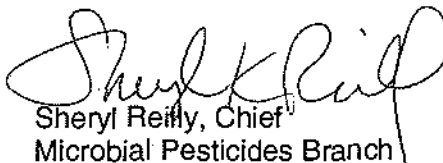
c) **Modeling.** Additional species-specific (e.g, ECB and SWCB for the Corn Belt), spatially-explicit, landscape modeling is needed to explore the durability of MON 89034 versus single-protein Bt corn products. Modeling should consider the impact of other Bt proteins in the landscape that may confer some cross-resistance (to Cry1A.105, in particular) and how such cross-resistance would impact the durability of MON 89034 in the Corn Belt (i.e., the use of simulation modeling). This is analogous to the species-specific simulation modeling that EPA required Monsanto do to support the use of natural refuge (instead of a structured refuge) for management of *H. virescens* and *H. zea* to the Cry1Ac and Cry2Ab2 proteins expressed in Bollgard II cotton.

If you do not modify your refuge proposals as described above, the application will be deemed deficient.

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for responding and subject to a new registration service fee.

Based on the content and timing of your response, the PRIA date for these applications may need to be renegotiated. Please contact Susanne Cerrelli of my staff at (703) 308-8077 should you have any questions or wish to schedule a meeting.

Sincerely,


Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

164



"GAO, YONG
[AG/1000]"
<yong.gao@monsanto.
com>

12/17/2007 10:00 AM

To: Susanne Cerrelli/DC/USEPA/US@EPA

cc: Mike Mendelsohn/DC/USEPA/US@EPA, "SCHNEIDER,
RUSSELL P [AG/1920]" <"@epamail.epa.gov>

bcc:

Subject: RE: New regulatory contact for Monsanto's MON 89034 corn

Dear Susanne,

I have talked to Russ who prefers that the letter should be directed to my attention at Monsanto's DC office address which is:

*Yong Gao
Regulatory Affairs Manager
Monsanto Company
1300 I Street, NW
Suite 450 East
Washington, DC 20005
Phone: (202) 383-2866
Fax: (202) 789-1748*

I am sure Russ has already contacted you on this. I am sending this note just as a confirmation and to introduce myself. I am also attaching, below, my contact information in St Louis for your reference. I look forward to working with you on MON 89034 and potential other products in the future.

Thank you.

Yong

Yong Gao, Ph.D.
*Regulatory Affairs Manager
Biotechnology
Monsanto Company
800 N. Lindbergh Blvd, E3NB
St Louis, Missouri 63167
(314) 694-2943 (office)
(314) 488-0971 (mobile)
(314) 694-3080 (fax)
yong.gao@monsanto.com*

-----Original Message-----

From: Cerrelli.Susanne@epamail.epa.gov
[mailto:Cerrelli.Susanne@epamail.epa.gov]
Sent: Friday, December 14, 2007 12:49 PM
To: BOGDANOVA, NATALIA N [AG/1000]

Cc: Mendelsohn.Mike@epamail.epa.gov; SCHNEIDER, RUSSELL P [AG/1920]; GAO, YONG [AG/1000]; LAHMAN, LINDA K [AG/1000]

Subject: Re: New regulatory contact for Monsanto's MON 89034 corn

Russ-

I received your latest email.

We are in the process of writing a letter concerning EPA Reg no. S24- LTA and -LTL (MON89034 and MON 89034x 88017). What address and contact information, do you prefer that we use? Please clarify.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

-----"BOGDANOVA, NATALIA N [AG/1000]"
<natalia.n.bogdanova@monsanto.com> wrote: -----
To: Susanne Cerrelli/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA
From: "BOGDANOVA, NATALIA N [AG/1000]"
<natalia.n.bogdanova@monsanto.com>
Date: 12/14/2007 12:29PM
cc: "SCHNEIDER, RUSSELL P [AG/1920]"
<russell.p.schneider@monsanto.com>, "GAO, YONG [AG/1000]"
<yong.gao@monsanto.com>, "LAHMAN, LINDA K [AG/1000]"
<linda.k.lahman@monsanto.com>
Subject: New regulatory contact for Monsanto's MON 89034 corn

Dear Mike and Susanne,

I would like to let you know that I have accepted a new role at Monsanto and will no longer be a contact person for MON 89034 corn. It was a pleasure working with you during the past several years and I wish you all the best.

I would like to introduce to you Yong Gao who will be a regulatory lead for MON 89034 corn from now on. Yong is very familiar with this product as he lead regulatory submissions to USDA and multiple international agencies during past two years. Please, in addition to Russ Schneider, contact him with any questions or information regarding MON 89034 at:

E-mail: yong.gao@monsanto.com
Tel: Office: (314) 694-2943; Mobile: (314) 488-0971.

Warmest Holiday Wishes and Happy New Year!

166

Natalia

Natolio N. Bogdanova, D.V.M.
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.,
St. Louis, MO 63167

Tel. (314) 694-3143

FAX (314) 694-3080

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"SCHNEIDER,
RUSSELL P
[AG/1920]"
<rusell.p.schnei
der@monsanto.c
om>

12/17/2007 09:00
AM

To: Susanne Cerrelli/DC/USEPA/US@EPA
cc
bcc
Subject: FW: New regulatory contact for Monsanto's MON 89034 corn

Susanne,

For whatever reason, I did not get this email, and fortunately Linda Lahman forwarded it. The letter should be addressed to Dr. Yong Gao, using my address, Monsanto Company, 1300 I St., NW, Suite 450E, Washington, DC 20005. Let me know when the letter is ready and I will pick it up. If after Wednesday, please contact Ms. Kate Walker, 202/383-2846, and she will pick up the letter.

Thanks,

Russ

-----Original Message-----

From: LAHMAN, LINDA K [AG/1000]
Sent: Monday, December 17, 2007 8:55 AM
To: SCHNEIDER, RUSSELL P [AG/1920]
Subject: FW: New regulatory contact for Monsanto's MON 89034 corn

-----Original Message-----

From: Cerrelli.Susanne@epamail.epa.gov [mailto:Cerrelli.Susanne@epamail.epa.gov]
Sent: Friday, December 14, 2007 12:49 PM
To: BOGDANOVA, NATALIA N [AG/1000]
Cc: Mendelsohn.Mike@epamail.epa.gov; SCHNEIDER, RUSSELL P [AG/1920]; GAO, YONG [AG/1000]; LAHMAN, LINDA K [AG/1000]
Subject: Re: New regulatory contact for Monsanto's MON 89034 corn

Russ-

I received your latest email.

We are in the process of writing a letter concerning EPA Reg no. 524- LTA and -LTL (MON89034 and MON 89034x 88017). What address and contact information, do you prefer that we use? Please clarify.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

-----"BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com> wrote:

To: Susanne Cerrelli/DC/USEPA/US@EPA, Mike Meridello/DC/USEPA/US@EPA
From: "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>
Date: 12/14/2007 12:29PM
cc: "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>, "GAO, YONG [AG/1000]" <yong.gao@monsanto.com>, "LAHMAN, LINDA K [AG/1000]" <linda.k.lahman@monsanto.com>
Subject: New regulatory contact for Monsanto's MON 89034 corn

Dear Mike and Susanne,

I would like to let you know that I have accepted a new role at Monsanto and will no longer be a contact person for MON 89034 corn. It was a pleasure working with you during the past several years and I wish you all the best.

I would like to introduce to you Yong Gao who will be a regulatory lead for MON 89034 corn from now on. Yong is very familiar with this product as he lead regulatory submissions to USDA and multiple international agencies during past two years. Please, in addition to Russ Schneider, contact him with any questions or information regarding MON 89034 at:

E-mail: yong.gao@monsanto.com
Tel: Office: (314) 694-2943; Mobile: (314) 488-0971.

Warmest Holiday Wishes and Happy New Year!

Natalia
Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.,
St. Louis, MO 63167

Tel. (314) 694-3143
FAX (314) 694-3080

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472797-01

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314) 694-3143

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

November 12, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Public Interest Document Supporting Registration of *Bacillus thuringiensis*
Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material
Necessary for Their Production in Insect-protected Corn MON 89034 and
MON 89034 x MON 88017 (EPA Files 5¹/₄-LTL and 524-LTA)

Dear Dr. Reilly:

On September 28, 2006 Monsanto submitted an application to register *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 proteins and the genetic material necessary for their production in insect-protected corn MON 89034 and MON 89034 x MON 88017 (EPA Files 5¹/₄-LTL and 524-LTA). On October 17, 2007 the Agency suggested that Monsanto should provide a Public Interest Document that would outline benefits of the products. We do so with the belief that because no new data required for registration is being submitted, the current PRIA date will not be impacted.

This submission contains administrative materials and a Public Interest Document for MON 89034 and MON 89034 x MON 88017. These documents have been classified as "A" - non- confidential documents that can be released to the public.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russ Schneider, Monsanto
Monsanto Regulatory Archives

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LIST OF SUBMITTED DOCUMENTS

Volume 1. Administrative Materials for the Submission of the Public Interest Document Supporting Registration of *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA Files 524-LTL and 524-LTA)

MRID Number _____

Volume 2. Public Interest Document Supporting Registration of *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA Files 514-LTL and 524-LTA)

MRID Number 47279701

Company Official: Natalia N Bogdanova November 12, 2007
Natalia N Bogdanova, D.V.M. Date
Regulatory Affairs Manager
(314) 694-3143

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Senior Director, Regulatory Affairs
(202) 383-2866



United States
Environmental Protection Agency
 Washington, DC 20460

☒
☐
☐

Registration
Amendment
Other

OPP Identifier
 Number

Application for Pesticide – Section I

1. Company/Product Number File Symbol 524-LTL and 524-LTA	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) MON 89034 and MON 89034 x MON 88017	PM # 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 1300 I (Eye) Street, N.W., Suite 450 East Washington, DC 20005 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Submission of the Public Interest Document Supporting Registration of Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA File 524-LTL and 524-LTA)

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other	(Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other	

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Russell P. Schneider		Title Senior Director, Regulatory Affairs		Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Affairs Manager			
4. Typed Name Natalia N. Bogdanova Tel. (314) 694-3143		5. Date November 12, 2007			

MONSANTO



VOLUME 1

Administrative Materials for the Submission of the Public Interest Document Supporting Registration of *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA Files 524-LTL and 524-LTA)

AUTHOR

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

SUBMISSION DATE

November 12, 2007

SUBMITTING REGISTRANT

Monsanto Company
1300 I (Eye) Street, NW
Suite 450 East
Washington, DC 20005

MONSANTO REFERENCE No.

06-CR-172-5

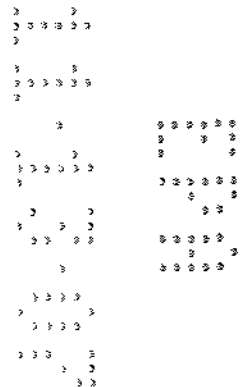


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Data Matrix (Form 8570-35)	5

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 1300 I (Eye) Street, N.W., Washington, DC 2005 (202) 383-2866	EPA Registration Number / File Symbol: 524-LTL and 524-LTA
Active Ingredient(s) and/or representative test compound(s): <i>Bt</i> CryIA.I05, Cry2Ab2 and Cry3BbI proteins and the genetic material (vectors ZMIR245 and ZMIR39) necessary for their production in MON 89034 and MON 89034 x MON 88017	Date: November 12, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 and MON 89034 x MON 88017

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements.]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date November 12, 2007	Typed or Printed Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager
---------------	---------------------------	---



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: November 12, 2007 EPA Reg. No./File Symbol: 524-LTL and 524-LTA Page 1 of 1

Applicant's/Registrant's Name & Address:

Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005

Product: MON 89034 and MON 89034 x MON 88017

Ingredient *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 and the genetic material necessary for its production (vectors ZMIR245 and ZMIR39) in MON 89034 and MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Volume 1. Administrative Materials for the Submission of the Public Interest Document Supporting Registration of <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA Files 524-LTL and 524-LTA)		Monsanto Company	OWN	This Submission
	Volume 2. Public Interest Document Supporting Registration of <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA Files 514-LTL and 524-LTA)		Monsanto Company	OWN	This Submission

Signature

Name and Title
Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

Date
November 12, 2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

U.S. ENVIRONMENTAL PROTECTION AGENCY

06-CR-172-5

Page 5 of 6

Monsanto Company



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.
Washington, D.C. 20460

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DATA MATRIX

Date: June 22, 2005

EPA Reg. No./File Symbol: 524-LTL and 524-LTA


Page 1 of 1

Applicant's/Registrant's Name & Address:

Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005

Product: MON 89034 and MON 89034 x MON 88017

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 and the genetic material necessary for its production (vectors ZMIR245 and ZMIR39) in MON 89034 and MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Submission
			Monsanto Company	OWN	This Submission
Signature 			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date November 12, 2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



"BOGDANOVA,
NATALIA N [AG/1000]"
<natalia.n.bogdanova@
monsanto.com>

10/26/2007 11:12 AM

To Susanne Cerrelli/DC/USEPA/US@EPA, "SCHNEIDER,
RUSSELL P [AG/1920]"
<russell.p.schneider@monsanto.com>

cc Mike Mendelsohn/DC/USEPA/US@EPA, "LAHMAN, LINDA
K [AG/1000]" <linda.k.lahman@monsanto.com>

bcc

Subject RE: MON 89034 and MON 89034 xMON88017 EPA Reg.
No. 524-LTA and 524-LTL

History: This message has been forwarded.

Dear Susanne,

Thank you for the update. The independent lab validation of the protein-based analytical method to detect Cry2Ab2 protein, which is specific for MON 89304 corn, is scheduled for completion for single seed and leaf by December 2008 and for grain - by February 2009.

Public interest document for MON 89034 and MON 89034 x MON88017 will be available in November.

Please, confirm that these timeframes do not affect PRIA date of June 10, 2008.

Thank you.

Natalia

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.,
St. Louis, MO 63167

Tel. (314) 694-3143
FAX (314) 694-3080

-----Original Message-----

From: Cerrelli.Susanne@epamail.epa.gov
[mailto:Cerrelli.Susanne@epamail.epa.gov]
Sent: Wednesday, October 17, 2007 2:12 PM
To: SCHNEIDER, RUSSELL P [AG/1920]
Cc: BOGDANOVA, NATALIA N [AG/1000]; Mendelsohn.Mike@epamail.epa.gov
Subject: MON 89034 and MON 89034 xMON88017 EPA Reg. No. 524-LTA and 524-LTL

Dear Russ Schneider and Natalia Bogdanova-

Mike mentioned that you were inquiring about the current status of the above 2 registrations. At this time the science reviews have not been finalized. We expect that by December 14,, 2007 all of the reviews will be completed and we will be able to give a definitive decision

about whether a SAP is needed or not. At this time a final determination has not been made about the need for a Science Advisory Panel.

In the interim, could you please advise us on the status of the independent lab validation of the Analytical methods?? I also believe it would be prudent to prepare and submit a public interest document/ benefits package in case we need to pursue conditional registrations of these products .

Please contact me if you have further questions concerning these products.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

This e-mail message may contain privileged and/or confidential information, and is intended to be received only by persons entitled to receive such information. If you have received this e-mail in error, please notify the sender immediately. Please delete it and all attachments from any servers, hard drives or any other media. Other use of this e-mail by you is strictly prohibited.

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Susanne
Cerrelli/DC/USEPA/US
10/17/2007 02:34 PM

To "SCHNEIDER, RUSSELL P [AG/1920]"
<russell.p.schneider@monsanto.com>
cc NATALIA N [AG/1000] BOGDANOVA, Mike
Mendelsohn/DC/USEPA/US
bcc

Subject Re: FW: nomenclature question for MON 89034

Dear Russ Schneider and Natalia Bogdanova-

Mike mentioned that you were inquiring about the current status of the above 2 registrations. At this time the science reviews have not been finalized. We expect that by December 14,, 2007 all of the reviews will be completed and we will be able to give a definitive decision about whether a SAP is needed or not. At this time a final determination has not been made about the need for a Science Advisory Panel.

In the interim, could you please advise us on the status of the independent lab validation of the Analytical methods??

I also believe it would be prudent to prepare and submit a public interest document/ benefits package in case we need to pursue conditional registrations of these products.

Please contact me if you have further questions concerning these products.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)


Rebecca
Edelstein/DC/USEPA/US

10/12/2007 03:58 PM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc John Kough/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA

bcc

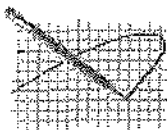
Subject Re: FYI-Fw: Re: Fw: GAO Study: Coordinated Framework
for the Regulation of Genetically Modified Agriculture
(360871).

Susanne,

I have not given OGC the whole tolerance exemption package. I was only consulting with them on some language to address issues related to issuing the tolerance exemption for all crops. The way I left things with OGC was that I was planning on finalizing my memo and then letting them comment on the full tolerance exemption when you send it to them.

Regarding the analytical method issue, have Sheryl and Janet made the call that we don't need Monsanto to submit an independent lab validation? I see that Janet has now said that we don't need a separate method for Cry1A.105, but I just want to make sure I understand correctly about the independent lab validation. Does it depend on whether GIPSA has validated the method or have they said we don't need it at all?

Rebecca
Susanne Cerrelli/DC/USEPA/US



Susanne
Cerrelli/DC/USEPA/US
10/12/2007 03:48 PM

To Rebecca Edelstein/DC/USEPA/US@EPA

cc John Kough/DC/USEPA/US@EPA

Subject FYI-Fw: Re: Fw: GAO Study: Coordinated Framework for
the Regulation of Genetically Modified Agriculture (360871).

Rebecca- More email!

Please let me know how OGC is responding to your requests.. They don't have the tolerance exemption package yet, or did you give them a copy?
hope this helps...

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

-----Forwarded by Susanne Cerrelli/DC/USEPA/US on 10/12/2007 03:44PM -----

To: Mike Mendelsohn/DC/USEPA/US@EPA, cerrelli.susanne@epa.gov
From: Sheryl Reilly/DC/USEPA/US
Date: 10/12/2007 02:27PM
cc: Alan Reynolds/DC/USEPA/US@EPA

182

Subject: Re: Fw: GAO Study: Coordinated Framework for the Regulation of Genetically Modified Agriculture (360871).

Susanne & Mike,

At the MPB General this a.m., I had an opportunity to talk with Janet and Mike McDavit about generic tolerances and also Mon 89034 issues we discussed yesterday.

As far as broad tolerance exemptions go, she says we can broaden tolerance exemptions only as far as the data can support a safety finding. So, for Vip3Aa, if the data only support the two we have, that's all we can do and to further broaden the tolerance exemption we would have to amend the exemption as more come in.

I also asked her about whether we could issue an unconditional for the Mon89034 product if we do not have an analytical method for both toxins. She said that it was not something we asked for initially so she thought it would be appropriate to do the conditional. Then I explained they did not submit a benefits package, which would be needed to do a Public Interest Determination for a conditional registration. I further explained that they would not have one trait without the other in the pending product. She thought about this and said that we could do an unconditional registration, with a caveat that if the toxin that does not have the analytical method were ever to be used as a single trait then they would have to submit an analytical method for that toxin.

From our conversation yesterday afternoon, it sounds like there are likely be data deficiencies that will not support the 5% refuge. I believe Sharlene has estimated that the IRM review will be finished around Thanksgiving. Do I need to contact OGC to see how long they need to review the final rule?

Sheryl K. Reilly, Ph.D.
Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
reilly.sheryl@epa.gov
703-308-8269 (phone)
703-308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

11:3
6
AM

DRAFT- PLEASE FEEL FREE TO COMMENT!!

Mike- I hope I got Rebecca's issues right. Here are the points if you can get to talk to Janet Monday.

Anticipate all secondary reviews will be complete by Nov 30, 2007.

Current PRIA date- June 10, 2008

The following issues were identified:

- 1) Product characterization and human health data submitted on event MON 89034, Cry1A.105, and Cry2Ab2 are sufficient to support the tol. exemption requests except that an analytical method for the detection of Cry1A.105 is needed. In addition, independent lab validations need to be submitted for the analytical detection methods for both Cry1A.105 and Cry2Ab2.
 - 2) Rebecca and John have pretty much completed Product characterization and tox evaluations. They are experiencing difficulty getting OGC to approve FQPA language concerning broad tolerance exemption (Mike I'll forward email.) for all crops.
 - 3) As indicated in our Agency letter dated January, 17, 2007, the expression data are necessary for popcorn and sweet corn in order to perform the IRM assessment. We do not have sufficient information (expression and activity) to complete an IRM assessment for sweet corn. We have no information on popcorn.
- Our recommendation is that Monsanto withdraw both the sweet corn and popcorn uses until such information can be generated and submitted to EPA to support these uses.
- 4) In addition, we do not have any document that would be used to make a Public Interest Finding should there be a conditional registration under 3(c)7(C). It would be prudent for Monsanto to prepare and submit such information to expedite the registration of these products should it be determined that a conditional registration is necessary.
 - 5) At this time, the IRM review is not complete but it appears that the IRM data are insufficient to support a reduced (5%)refuge. We are 99% sure

we don't need an SAP because the data are inadequate. Sharlene and Alan suggested that additional data would be required for 5% refuge but the product could be registered with the prior 20% refuge.

Specific questions for Janet:

A) B) Can Janet discuss broad tolerance exemption issue with OGC, and explain why BPPD pursuing broader exemptions? If not does she recommend that the tolerance piece be dealt with separate from the review so we can finalize the evaluation and notify Monsanto about analytical method needs??

C) If "A)" is not a show stopper- Is the proposal ok to require additional IRM data for 5% refuge as a term or condition of registration but register the product with the prior 20% refuge. If we pursue conditional registration, at what point do we renegotiate because of lacking public interest document and deficiencies

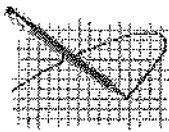
D) Is it ok to go ahead and tell Monsanto to send the Public interest document in ASAP??

E) Additional Recommendations about reg. process/ letters /extensions/ renegotiating dates??

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)



Mike
Mendelsohn/DC/USEPA
/US

10/12/2007 03:44 PM

To Rebecca Edelstein/DC/USEPA/US@EPA

cc Susanne Cerrelli/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA, John
Kough/DC/USEPA/US@EPA, Alan

bcc

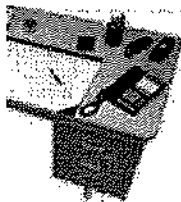
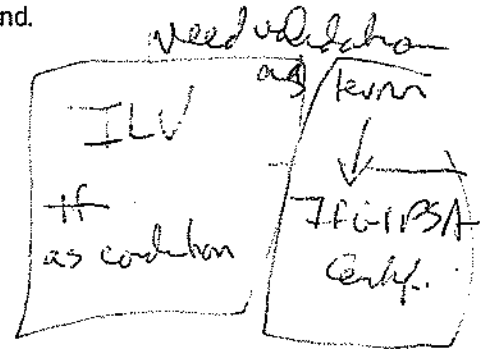
Subject MON 89034

Rebecca and Susanne,

Since Sheryl had an opportunity to discuss these issues with Janet at the MPB General, I don't need to discuss on Monday. I suggest listing the ILVs as missing and finalizing the review, but indicating that GIPSA certification would fulfill the ILV requirement. We have both had ILVs before registration and required them as conditions. Janet seems OK with registering with only the Cry2Ab2 method. We will probably need a discussion in the Cry1A.105 final rule that explains why the Cry2Ab2 method will work for MON 89034. Maybe we can discuss more Monday. Thanks. Have a great weekend.

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
<http://www.epa.gov/pesticides/biopesticides>

----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 10/12/2007 03:12 PM -----



Sheryl
Reilly/DC/USEPA/US
10/12/2007 02:27 PM

To Mike Mendelsohn/DC/USEPA/US@EPA,
cerrelli.susanne@epa.gov
cc Alan Reynolds/DC/USEPA/US@EPA

Subject Re: Fw: GAO Study: Coordinated Framework for the
Regulation of Genetically Modified Agriculture (36087 t)

Susanne & Mike,

At the MPB General this a.m., I had an opportunity to talk with Janet and Mike McDavit about generic tolerances and also Mon 89034 issues we discussed yesterday.

As far as broad tolerance exemptions go, she says we can broaden tolerance exemptions only as far as the data can support a safety finding. So, for Vip3Aa, if the data only support the two we have, that's all we can do and to further broaden the tolerance exemption we would have to amend the exemption as more come in.

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Sheryl K. Reilly, Ph.D.
Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
reilly.sheryl@epa.gov
703-308-8269 (phone)
703-308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

Rebecca
Edelstein/DC/USEPA/US

10/12/2007 02:55 PM

To: Susanne Cerrelli/DC/USEPA/US@EPA

cc: Mike Mendelsohn/DC/USEPA/US@EPA

bcc

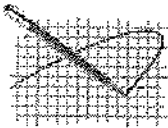
Subject: Re: Discussion points for Mike's Monday Mtg. with Janet-
MON 89034 - EPA Reg. No 524-LTA and -LTL

Mike and Susanne,

If the main thing you are going to be discussing with Janet on Monday is the analytical detection method, I would also like to be there, if that's okay (I'm planning on being in the office on Monday anyway). It is strictly a policy call, but I want to make sure everyone is clear on what we have and don't have for this product. And I want to make sure I find out what we need and when. I'm reviewing another product where we don't have an independent lab validation of the analytical method, so I need to know if that's a requirement prior to registration or not.

Thanks,

Rebecca
Susanne Cerrelli/DC/USEPA/US



Susanne
Cerrelli/DC/USEPA/US

10/12/2007 02:42 PM

To: Rebecca Edelstein/DC/USEPA/US@EPA

cc: Mike Mendelsohn/DC/USEPA/US@EPA

Subject: Re: Discussion points for Mike's Monday Mtg. with Janet-
MON 89034 - EPA Reg. No 524-LTA and -LTL

Rebecca-

I appreciate the clarifications and corrections!

Mike was going to try to get to see Janet before noon on Monday, as we were told that she will be gone the rest of next week.

Rebecca Pardon my naivete. I thought there may be away to get around the absence of the Cry1A.105 method if there was no risk concerns based on what is currently registered, and there is a commitment to submit the Cry1A.105 method in a timely fashion.

I honestly don't know how to handle the gap. I am hoping Janet could tell us our options.

so for A) below I suggest changing it to:

A) Is the lack of a validated method- mean we can not even conditionally register the product, since it is needed to support tolerance exemption? or are there other options BPPD can consider? Is this a SHOW STOPPER??

Mike -

Do I need to set up this meeting for you and Janet, or is it a regular weekly meeting you have

with her @ pending stuff?? If you are setting it up do you mind cc'ing Rebecca and I?

-Thanks!!

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

-----Rebecca Edelstein/DC/USEPA/US wrote: -----

To: Susanne Cerrelli/DC/USEPA/US@EPA
From: Rebecca Edelstein/DC/USEPA/US
Date: 10/12/2007 01:34PM
cc: Alan Reynolds/DC/USEPA/US@EPA, John Kough/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Sharlene Matten/DC/USEPA/US@EPA
Subject: Re: Discussion points for Mike's Monday Mtg. with Janet- MON 89034 - EPA Reg. No 524-LTA and -LTL

Susanne,

Just a few points of clarification... We don't need the validated analytical detection method for safety, and it's not normally needed for tolerance exemptions. However, it has been BPPD's policy since Starlink to require a validated analytical detection method for the active ingredient in PIPs. So, it is a policy decision. I'm not sure I follow your suggestion to use the existing method in an interim period.

Regarding the tolerance exemption for all crops, I think I have come up with a solution to address Keith's comments and have sent my proposal to him (and cc'd others). I asked him to let me know if he had any issues with my proposal, and I haven't heard back from him, so I'm hoping the issue is resolved.

Also, when is this meeting?

Rebecca
Susanne Cerrelli/DC/USEPA/US

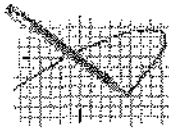
Sus
anne
e
Cer
relli
/DC
/US
EP
A/U
S

ToMike Mendelsohn/DC/USEPA/US@EPA

ccRebecca Edelstein/DC/USEPA/US@EPA, John
Kough/DC/USEPA/US@EPA, Alan
Reynolds/DC/USEPA/US@EPA, Sharlene
Matten/DC/USEPA/US@EPA

10/1
2/20
07

SubjectDiscussion points for Mike's Monday Mtg. with
Janet- MON 89034 - EPA Reg. No 524-LTA and
-LTL



Sharlene
Matten/DC/USEPA/US
11/20/2006 03:37 PM

To Mike Mendelsohn/DC/USEPA/US@EPA, Susanne
Cerrelli/DC/USEPA/US@EPA
cc Alan Reynolds/DC/USEPA/US@EPA, Tessa
Milofsky/DC/USEPA/US@EPA, Mika
Hunter/DC/USEPA/US@EPA, Patricia

bcc

Subject IRM and Benefits screening for MON 89034 and MON 89034
X MON 88017

Mike and Susanne --

The IRM package for MON 89034 passes the initial screen. However, no one mentioned that the registration application includes sweet corn and popcorn. The IRM plan for sweet corn is for a non-structured refuge because of the cultural practices and growing season (shorter) -- overwintering destruction methods. The IRM plan for popcorn is identical to that of field corn. I think I may have some questions about the modeling that was done, but that will come later.

The IRM package for MON 89034 X MON 88017 is deficient. There is no bridging rationale provided. At a minimum, Monsanto must provide information about the dose of the stacked product vs. each single gene product and the expression of the stacked product vs. each single gene product.

There is no benefits package for either new active ingredient, Cry1A.105 or Cry2Ab2, in corn. Every Bt corn PIP, with the exception of the NK Bt 11, was conditionally registered registered under 3(c)7(C) and therefore required the Agency to make a public interest finding based on a benefits assessment. Therefore, Monsanto should provide a public interest document. I expect there will be conditions of registration and these registrations will be time-limited.

Sharlene



Administrative Materials for Supplemental Information to Address EPA Questions
Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn
MON 89034 and MON 89034 x MON 88017
(MRID 46951400 and 46951300)

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

May 9, 2007

Monsanto Company
1300 I (Eye) Street, NW
Suite 450 East
Washington, DC 20005

06-CR-172-3

Page 1 of 9

(19)

1

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.....


3


Data Matrix (Form 8570-35)

[illegible]

Calendar Entry
Meeting

☒ Notify me ☐ Mark Private ☐ Pencil In

Subject	Teleconference Consultation concerning FR's and procedure for stacks with "old" AIs			Chair	Susanne Cerrelli/DC/U
When	Starts	Tue 06/26/2007	09:30 AM	Where	Location BPPD sm telephone
	Ends	Tue 06/26/2007	10:00 AM		Reserved No rooms reserved
				<input type="checkbox"/> Specify a different time zone	
Invitees	Invited	The following invitees have been invited			
	Required (to)	Chris Kaczmarek/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA			
	FYI (bcc)	Sheryl Reilly/DC/USEPA/US@EPA			
Scheduler					

Show <input checked="" type="radio"/> Status <input type="radio"/> Summary <input type="radio"/> Details 	Invitees	Status
	Susanne Cerrelli/DC/USEPA/	Accepted
	Required	
	Chris Kaczmarek/DC/USE	Accepted
	Keith Matthews/DC/USEP	Accepted
	Mike Mendelsohn/DC/USE	Accepted
	Scheduled Rooms	Status
Scheduled Resources	Status	

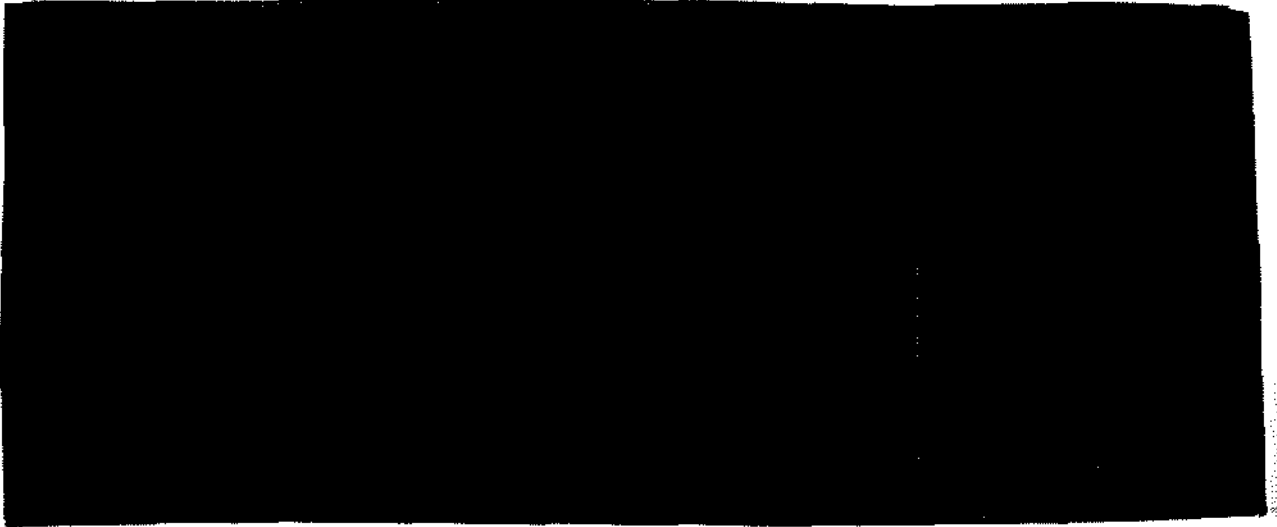
Description

Thanks everyone! I am just seeking a short consultation to clarify current Policy for stacked pips.

Mike M. has some comments and questions concerning the email below addressing changes needed to a federal register notice concerning a PIP that is stacked with a previously registered pip (MON 89034x MON 88017). Chris requested that we specifically mention in the notice: a changed use pattern for the previously registered pip (MON 88017) when we announce the stacked pip in the FR. Mike M, mentioned that this issue has arisen before and was dealt with differently by OPP in prior years. For OGC's convenience, I can teleconference you in to discuss the issue, but you will need to print out the file below that has Chris's comments. I am not here Thursday June 21. Chris and Keith, please inform me what phone numbers you

prefer to be teleconferenced at for this Tuesday meeting.

THANKS!!!





United States
Environmental Protection Agency
 Washington, DC 20460

☒
☐
☐

Registration
Amendment
Other

OPP Identifier
 Number

Application for Pesticide – Section I

1. Company/Product Number File Symbol 524-LTL and 524-LTA	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification
Company/Product (Name) MON 89034 and MON 89034 x MON 88017	PM # 92	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 1300 I (Eye) Street, N.W., Suite 450 East Washington, DC 20005 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Submission of supplemental information for MRIDs 46951300, 46951302, 46951303, 46951400, 46951402, and 46951403, to facilitate review of studies submitted for the registration of MON 89034 and MON 89034 x MON 88017.

Section – III

Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container

Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Russell P. Schneider	Title Director, Regulatory Affairs	Telephone No. (Include Area Code) (202) 383-2866
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Manager	
Typed Name Natalia N. Bogdanova	5. Date May 9, 2007	
Tel. (314) 694-3143		

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 1300 I (Eye) Street, N.W., Washington, DC 2005 (202) 383-2866	EPA Registration Number / File Symbol: 524-LTL and 524-LTA
Active Ingredient(s) and/or representative test compound(s): <i>B.t. Cry1A.105, Cry2Ab2, and Cry3Bb1</i> and the genetic material (vectors ZMIR245 and ZMIR39) necessary for their production in MON 89034 and MON 88017.	Date: May 9, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 and MON 89034 x MON 88017

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA, and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

May 9, 2007

Typed or Printed Name and Title

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager



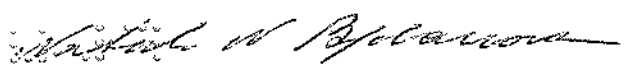
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: May 9, 2007		EPA Reg. No./File Symbol: 524-LTA and 524-LTL		Page 1 of 2	
Applicant's/Registrant's Name & Address: Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005		Product: MON 89034 and MON 89034 x MON 88017			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, and Cry3Bb1 and the genetic material necessary for its production (vectors ZMIR245 and ZMIR39) in MON 89034 and MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Volume 1. Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)		Monsanto Company	OWN	This Submission
	Volume 2. Response to EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)		Monsanto Company	OWN	This Submission
885.1100	Volume 3. Supplemental Information for MRID No. 46951302 "Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis"		Monsanto Company	OWN	This Submission
885.1100	Volume 4. Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034"		Monsanto Company	OWN	This Submission
Signature 			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date May 9, 2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

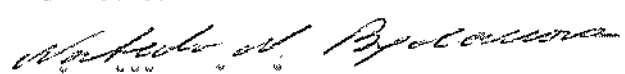


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

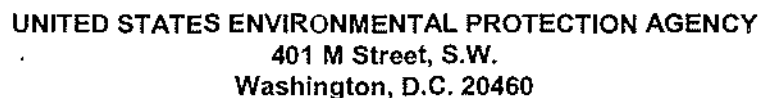
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: May 9, 2007		EPA Reg. No./File Symbol: 524-LTA and 524-LTL		Page 2 of 2	
Applicant's/Registrant's Name & Address: Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005		Product: MON 89034 and MON 89034 x MON 88017			
Ingredient <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2, and Cry3Bb1 and the genetic material necessary for its production (vectors ZMIR245 and ZMIR39) in MON 89034 and MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Volume 5. Supplemental Information for MRID No. 46951303 "Assessment of the CryIA.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials"		Monsanto Company	OWN	This Submission
885.1100	Volume 6. Supplemental Information for MRID No. 46951403 "Assessment of the CryIA.105 and Cry2Ab2 Protein Levels in Tissues of Insect-protected Corn MON 89034 Produced in 2005 U.S. Field Trials"		Monsanto Company	OWN	This Submission
Signature 			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date May 9, 2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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Date: June 22, 2005	EPA Reg. No./File Symbol: 524-LTA and 524-LTL	Page 1 of 2
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Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005

Page 1 of 2

Product: MON 89034 and MON 89034 x MON 88017

Ingredient	<i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, and Cry3Bb1 and the genetic material necessary for their production (vectors ZMIR245 and ZMIR39) in MON 89034 and MON 88017
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Submission
			Monsanto Company	OWN	This Submission
			Monsanto Company	OWN	This Submission
			Monsanto Company	OWN	This Submission
Signature			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date May 9, 2007	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

100

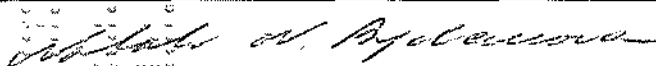


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: May 9, 2007		EPA Reg. No./File Symbol: 524-LTL and 524-LTA		Page 2 of 2	
Applicant's/Registrant's Name & Address: Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005		Product: MON 89034 and MON 89034 x MON 88017			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, and Cry3Bb1 and the genetic material necessary for their production (vectors ZMIR245 and ZMIR39) in MON 89034 and MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Submission
			Monsanto Company	OWN	This Submission
Signature 			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date May 9, 2007

MON 89034

201



MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subj: Re-classification of the information provided in the submission of supplemental information to address EPA questions regarding applications 524-LTL and 524-LTA to register insect-protected corn MON 89034 and MON 89034 x MON 88017 (MRID 47079402)

This letter is in response to conversations with the Agency regarding re-classification of information submitted on March 9, 2007 in the response to EPA questions regarding application to register insect-protected corn MON 89034 and MON 89034 x MON 88017.

By the way of this letter Monsanto amends the confidentiality claims for the information submitted with the above petitions to re-classify it from current category "A" (non-confidential documents that can be released to the public) to category "B" (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers). Monsanto considers this information to be a competitive advantage because it contains details concerning MON 89034 that are intended for the regulatory assessment and that could be potentially used by multinational companies to develop and register their products. Please consider the tables in Monsanto letters from March 9, 2007 revised as follows:

Monsanto Reference Numbers
04- CR-135E-3
04-CR-138E-3

$\begin{array}{ccccccc} & & & & & 5 & 3 & 2 \\ & & & & & 7 & 2 & 3 \\ 1 & 3 & 2 & 5 & 2 & 3 & & \\ 1 & & 5 & & 1 & & & \\ 1 & & 3 & & 4 & & & \\ 3 & & & & 2 & & & \end{array}$

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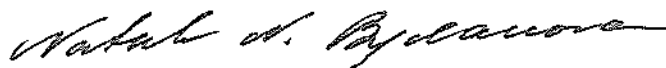
$\begin{array}{ccccccc} & & & & & 3 & 2 & 5 & 2 \\ & & & & & 1 & & 2 & 5 & 2 \\ 1 & 2 & 1 & 2 & & & & & & \\ & & & & & & & & & \\ & & & & & & & & & \\ 1 & & & & & & & & & \\ 1 & & 1 & 1 & 2 & & & & & \end{array}$

202

Volume	Old Category	New Category	Document
N/A	A	A	Cover letter
N/A	A	A	Transmittal document
1	A	A	Administrative volume
1	C	C	Confidential statement of formula
2	A	B	Supplemental information
3	B	B	Efficacy report

Should you require any additional information regarding this letter please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,



Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Susanne Cerrelli, EPA/OPP/BPPD
Russ Schneider, Monsanto
Regulatory Archives

Monsanto Reference Numbers
04- CR-135E-3
04-CR-138E-3

203

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314) 694-3143

May 11, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subj: Re-classification of petitions to amend 40 CFR §174.453 and 40 CFR §174.454 to establish permanent exemption from the requirement of a tolerance for *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 insecticidal proteins and the genetic material necessary for their production when used as plant-incorporated protectants in all crops and agricultural commodities.

EPA Petition Numbers 6F7142 and 6F7143

Dear Dr. Reilly:

This letter is in response to conversations with the Agency regarding re-classification of information submitted in tolerance petitions for Cry1A.105 and Cry2Ab2 proteins produced in insect-protected corn MON 89034.

On March 9, 2007 petitions were submitted to EPA to amend 40 CFR §174.453 and 40 CFR §174.454 to establish permanent exemptions from the requirement of a tolerance for *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 insecticidal proteins and the genetic material necessary for their production when used as plant-incorporated protectants in all crops and agricultural commodities.

By the way of this letter Monsanto amends the confidentiality claims for the information submitted with the above petitions to re-classify it from current category "B" to category "A" (materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer). Please consider the tables in Monsanto letters from March 9, 2007 revised as follows:

Monsanto Reference Numbers
04- CR-135E-3
04-CR-138E-3

204

Volume	Old Category	New Category	Document
<i>Cry1A.105 petition</i>			
N/A	A	A	Cover letter
1	B	A	Petition to Amend 40 CFR §174.453 to Establish Permanent Exemption from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1A.105 Insecticidal Protein and the Genetic Material Necessary for Its Production When Used as Plant-incorporated Protectant in All Crops and Agricultural Commodities.
N/A	A	A	Draft Federal Register Notice
<i>Cry2Ab2 petition</i>			
N/A	A	A	Cover letter
1	B	A	Petition to Amend 40 CFR §174.454 to Establish Permanent Exemption from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry2Ab2 Insecticidal Protein and the Genetic Material Necessary for Its Production When Used as Plant-incorporated Protectant in All Crops and Agricultural Commodities.
N/A	A	A	Draft Federal Register Notice

Should you require any additional information regarding this letter please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Susanne Cerrelli, EPA/OPP/BPPD
Russ Schneider, Monsanto
Regulatory Archives

Monsanto Reference Numbers
04- CR-135E-3
04-CR-138E-3

505



U. S. Environmental Protection Agency
Office of Prevention, Pesticides, and Toxic Substances (OPPTS)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

DOCKET VERIFICATION AND CERTIFICATION FORM
For Internal OPPTS Use Only

Title of Action: Pesticide Products; Registration Applications for *Bacillus thuringiensis* Cry1A.105 protein and the genetic material (Vector ZMIR 245)necessary for its production in event MON 89034 corn (OECD Unique Identifier: MON-89034-3) and *Bacillus thuringiensis* Cry2Ab2 protein and the genetic material (Vector ZMIR 245) necessary for its production in event MON 89034 corn (OECD Unique Identifier: MON-89034-3) .

RIN #: 2070- **Docket ID #:** EPA-HQ-OPP-2007-0208 **FRL#:** 8129-7

Docket Title: Pesticide Products; Registration Applications for *Bacillus thuringiensis* Cry 1A.105 and Cry2Ab2 insecticidal proteins in all crops and agricultural commodities

Contact Information: **Name:** Susanne Cerrelli **Phone #:** 703-308-8077

Legacy Information: ; **FDMS Docket #** EPA-HQ-OPP-2007-0346

Program Lead's Verification: I have reviewed the docket and verified the following:

- All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- Documents containing copyrighted, CBI, or otherwise protected information have been identified to allow for "special" processing by the appropriate Docket Staff.
- The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER (FR).
- **COMMENTS:** Susanne Cerrelli is the primary Docket Contact Person. Estimated FR publication date is 07/11/2007

Date 04/16/07 **Initials:** *Susanne Cerrelli* **Phone #:** 703-308-8077

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- The Docket ID # identified above matches our records.
- The documents identified in the attached Docket Index have been received by the OPP Docket Staff.
- The documents have been properly processed for inclusion in EPA FDMS Dockets, as appropriate.
- The documents either already are in the docket or are being processed for inclusion in the docket.
- **COMMENTS:**

Date: 04/16/07 **Signature:** *Anth [Signature]* **Phone #:** 703-308-8077

Program Lead's Certification: I hereby certify that:

- I have completed the verification above.
- I have submitted to the Docket Manager all of the documents that I identified needed to be updated or added to the docket.
- I have obtained the Docket Manager's sign-off.
- The docket is complete and ready for public release.
- **COMMENTS:**

Date 04/16/07 **Signature:** *Susanne Cerrelli* **Phone #:** 703-308-8077

6/28/07

Attachment: List of Documents for Docket ID # EPA-HQ-2007-0208 new items as of 05/24/06 07

Document Title		Source Information: Author (Last, First Name); Organization; Citation	Date of Document	1) CBI 2) Other Protected, e.g., Studies 3) Copyrighted
1	Cover Letter	Monsanto	9/29/2006	
2	Administrative volume	Monsanto	9/29/2006	
3	Transmittal Document MRID 46951300 Monsanto Company (2006) Submission of Product Chemistry, Efficacy, Exposure and Risk Data in Support of the Application for Registration of MON 89034 x 88017. Transmittal of 6 Studies.	Monsanto	9/29/2006	
4	Cover letter	Monsanto	9/28/2006	
5	Administrative volume (redacted copy)	Monsanto	9/28/2006	
6	Transmittal Document MRID 46951400 -Monsanto Company (2006) Submission of Efficacy, Toxicity, Residue, Environmental Fate, Exposure and Risk Data in Support of the Application for Registration of MON 89034. Transmittal of 30 Studies.	Monsanto	9/2006	
7	Cover letter	Monsanto	3/8/07	
8	Administrative volume (redacted)	Monsanto	3/9/07	
9	Transmittal Document MRID 47079400 Monsanto Co. (2007) Submission of Efficacy Data in Support of the Application for Registration of MON 89034 X 88017. Transmittal of 2 Studies.	Monsanto	3/9/07	
10	CD of data MRID 46951301- 46951306 MRID 46951401- 46951430 MRID 47079402- 47079403	Monsanto	2006 and 3/9/07	2
11	Letter to reclassify MRID 47079402	Monsanto	5/11/2007	

MONSANTO



Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314)-694-3143

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<http://www.monsanto.com>

May 11, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Response to questions from EPA for insect-protected corn MON 89034 and MON 89034 x MON 88017 and supplemental information for MRIDs 46951302, 46951303, 46951402, and 46951403

EPA Petition Numbers 6F7142 and 6F7143
EPA File Symbols: 524-LTA and 524-LTL

Dear Dr. Reilly:

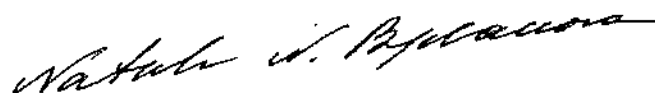
This letter is in response to the Agency's request from April 23, 2007 to address questions pertaining to Monsanto's application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in corn products MON 89034 and MON 89034 x MON 88017.

Responses to the Agency's questions are included in volume 2 of this submission. Supplemental information requested by the Agency for MRIDs 46951302, 46951303, 46951402, and 46951403 is provided in volumes 3-6. This submission includes documents that have been classified as 'A' - non-confidential documents that can be released to the public, or 'B' - data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers. A pdf file of documents classified as 'A' is included with this letter. Volumes 3 - 6 contain Standard Operating Procedures used in studies that were submitted in support of the registration. Monsanto considers this information to be of a competitive nature because the methods described are components of an overall process established after years of refinement to most efficiently and effectively generate data on products for regulatory and discovery work.

Volume	Document	Category	Hard copy	pdf. file for E-docket
N/A	Cover Letter	A	✓	✓
1	Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	A	✓	✓
2	Responses to EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	A	✓	✓
3	Supplemental Information for MRID No. 46951302 "Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis"	B	✓	
4	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034"	B	✓	
5	Supplemental Information for MRID No. 46951303 "Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials"	B	✓	
6	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-protected Corn MON 89034 Produced in 2005 U.S. Field Trials"	B	✓	

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,



Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto
Monsanto Regulatory Files

MONSANTO



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
1300 I (Eye) Street, NW
Suite 450 East
Washington, DC 20005

**REGULATORY ACTION IN SUPPORT OF WHICH
THIS DOCUMENT IS SUBMITTED**

Administrative Materials for the Registration of Insect-protected Corn MON 89034 and
MON 89034 x MON 88017 (EPA File 524-LTA and 524-LTL)

TRANSMITTAL DATE

May 11, 2007

MONSANTO REFERENCE No.

06-CR-172-3

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

- Volume 1.** Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

MRID Number _____

- Volume 2.** Responses to EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

MRID Number 47127501

- Volume 3.** Supplemental Information for MRID No. 46951302 "Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis"

MRID Number 47127502

- Volume 4.** Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034"

MRID Number 47127503

- Volume 5.** Supplemental Information for MRID No. 46951303 "Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials"

MRID Number 47127504

Volume 6. Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-protected Corn MON 89034 Produced in 2005 U.S. Field Trials"

MRID Number 47127505

Company Official: *Natalia N. Bogdanova* May 11, 2007
Natalia N Bogdanova, D.V.M. Date
Regulatory Affairs Manager
(314) 694-3143

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Director, Regulatory Affairs
(202) 383-2866

BOGDANOVA, NATALIA N [AG/1000]

From: Cerrelli.Susanne@epamail.epa.gov
Sent: Wednesday, May 23, 2007 3:38 PM
To: BOGDANOVA, NATALIA N [AG/1000]
Subject: Re: Responses to EPA questions RE: MON 89034 and MON 89034 x MON88017 (524-LTL and 524-LTA)



Letter to re-classify Letter to re-classify
CBI cate... CBI cate...

Natalia,

I just realized that I need an electronic copy of the petitions for these two products now that they have been reclassified for the docket. Can you please send me a disk with your next mailing with a copy of the petitions?

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

"BOGDANOVA,
NATALIA N
[AG/1000]"
<natalia.n.bogda
nova@monsanto.co
m>

05/11/2007 10:39
PM

To
Susanne Cerrelli/DC/USEPA/US@EPA,
Mike Mendelsohn/DC/USEPA/US@EPA
cc
"SCHNEIDER, RUSSELL P [AG/1920]"
<russell.p.schneider@monsanto.com
>, "LAHMAN, LINDA K [AG/1000]"
<linda.k.lahman@monsanto.com>,
"BOGDANOVA, NATALIA N [AG/1000]"
<natalia.n.bogdanova@monsanto.com
>

Subject
Responses to EPA questions RE:
MON 89034 and MON 89034 x
MON88017 (524-LTL and 524-LTA)

Susanne,

per our telephone conversation today attached are two letters: first - to address re-classification of information provided in the supplemental submission MRID 47079402 and

MONSANTO



Natalia N. Bogdanovo, D.V.M.
Regulatory Affairs Manager
(314)-694-3143

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

May 11, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Response to questions from EPA for insect-protected corn MON 89034 and MON 89034 x MON 88017 and supplemental information for MRIDs 46951302, 46951303, 46951402, and 46951403

EPA Petition Numbers 6F7142 and 6F7143
EPA File Symbols: 524-LTA and 524-LTL

Dear Dr. Reilly:

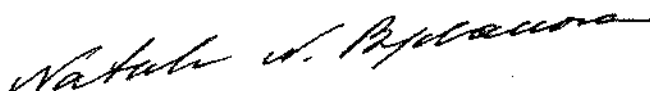
This letter is in response to the Agency's request from April 23, 2007 to address questions pertaining to Monsanto's application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in corn products MON 89034 and MON 89034 x MON 88017.

Responses to the Agency's questions are included in volume 2 of this submission. Supplemental information requested by the Agency for MRIDs 46951302, 46951303, 46951402, and 46951403 is provided in volumes 3-6. This submission includes documents that have been classified as 'A' - non-confidential documents that can be released to the public, or 'B' - data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers. A pdf file of documents classified as 'A' is included with this letter. Volumes 3 - 6 contain Standard Operating Procedures used in studies that were submitted in support of the registration. Monsanto considers this information to be of a competitive nature because the methods described are components of an overall process established after years of refinement to most efficiently and effectively generate data on products for regulatory and discovery work.

Volume	Document	Category	Hard copy	pdf. file for E-docket
N/A	Cover Letter	A	✓	✓
1	Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	A	✓	✓
2	Responses to EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	A	✓	✓
3	Supplemental Information for MRID No. 46951302 "Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis"	B	✓	
4	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034"	B	✓	
5	Supplemental Information for MRID No. 46951303 "Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials"	B	✓	
6	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-protected Corn MON 89034 Produced in 2005 U.S. Field Trials"	B	✓	

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,



Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto
Monsanto Regulatory Files

MONSANTO



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
1300 I (Eye) Street, NW
Suite 450 East
Washington, DC 20005

**REGULATORY ACTION IN SUPPORT OF WHICH
THIS DOCUMENT IS SUBMITTED**

Administrative Materials for the Registration of Insect-protected Corn MON 89034 and
MON 89034 x MON 88017 (EPA File 524-LTA and 524-LTL)

TRANSMITTAL DATE

May 11, 2007

MONSANTO REFERENCE No.

06-CR-172-3

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

- Volume 1.** Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

MRID Number _____

- Volume 2.** Responses to EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

MRID Number 47127501

- Volume 3.** Supplemental Information for MRID No. 46951302 "Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis"

MRID Number 47127502

- Volume 4.** Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034"

MRID Number 47127503

- Volume 5.** Supplemental Information for MRID No. 46951303 "Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials"

MRID Number 47127504

Volume 6. Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-protected Corn MON 89034 Produced in 2005 U.S. Field Trials"

MRID Number 47127505

Company Official: *Natalia N. Bogdanova* May 11, 2007
Natalia N Bogdanova, D.V.M. Date
Regulatory Affairs Manager
(314) 694-3143

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Director, Regulatory Affairs
(202) 383-2866

MONSANTO



Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314) 694-3143

MONSANTO COMPANY
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<http://www.monsanto.com>

May 11, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subj: Re-classification of the information provided in the submission of supplemental information to address EPA questions regarding applications 524-LTL and 524-LTA to register insect-protected corn MON 89034 and MON 89034 x MON 88017 (MRID 47079402)

Dear Dr. Reilly:

This letter is in response to conversations with the Agency regarding re-classification of information submitted on March 9, 2007 in the response to EPA questions regarding application to register insect-protected corn MON 89034 and MON 89034 x MON 88017.

By the way of this letter Monsanto amends the confidentiality claims for the information submitted with the above petitions to re-classify it from current category "A" (non-confidential documents that can be released to the public) to category "B" (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers). Monsanto considers this information to be a competitive advantage because it contains details concerning MON 89034 that are intended for the regulatory assessment and that could be potentially used by multinational companies to develop and register their products. Please consider the tables in Monsanto letters from March 9, 2007 revised as follows:

Monsanto Reference Numbers

04-CR-135E-3

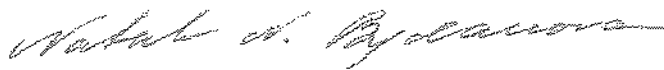
04-CR-138E-3

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Volume	Old Category	New Category	Document
N/A	A	A	Cover letter
N/A	A	A	Transmittal document
1	A	A	Administrative volume
1	C	C	Confidential statement of formula
2	A	B	Supplemental information
3	B	B	Efficacy report

Should you require any additional information regarding this letter please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,



Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Susanne Cerrelli, EPA/OPP/BPPD
Russ Schneider, Monsanto
Regulatory Archives

Monsanto Reference Numbers
04- CR-135E-3
04-CR-138E-3

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Susanne
Cerrelli/DC/USEPA/US
05/03/2007 08:29 AM

To Sharlene Matten/DC/USEPA/US, Alan
Reynolds/DC/USEPA/US
cc Mike Mendelsohn/DC/USEPA/US

bcc

Subject memorandum of understanding dated February 5, 2007 from
Monsanto - Comments from EPA

Are there any additional comments that we should send Monsanto concerning their February 5, 2007 letter that followed our meeting on January 25, 2007?

Sharlene gave me the following feedback yesterday. please let Susanne know if there are additions or corrections to the below item.

We wish that the following item be corrected that is present in Monsanto's February 5, 2007 letter concerning "Memorandum of understanding; EPA Petition numbers 6F7142 and 6F7143; EPA File symbols: 524-LTA and 524-LTL."

For item 2 we wish to make the following correction. Separate information needs to be developed to support the popcorn use. We disagree that expression data (information) developed for sweet corn can be applied to popcorn.

Please note we plan to add some items to today's biotech meeting.

(1) DNA vs ELISA quantification (feedback what is EPA's purpose of validation when have tol. exemption)?

(2) Should we renegotiate dates when company gives additional info later that we need (What is Agency Policy @ late submissions and PRIA dates)?

(a) MARCH 7 irm RESPONSE

(b) Sweet corn expression data that is being developed still

Thanks!

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

221

Calendar Entry

Meeting

☒ Notify me

☐ Mark Private



☐ Pencil In

Subject	Analytical method issue /Validation for MON 89034 and MON 89034 x MON88017 see details below			Chair	Susanne Cerrelli/DC/U
When	Starts	Tue 05/01/2007	02:30 PM	Where	Location BPPD Lib
	Ends	Tue 05/01/2007	03:30 PM		Reserved No rooms reserved
Invitees	Invited	The following invitees have been invited			
	Required (to)	Annabel Waggoner/DC/USEPA/US@EPA, Carl Etsitty/DC/USEPA/US@EPA, Janet Andersen/DC/USEPA/US@EPA, John			
	Additional	Select additional invitees below			
	Required (to)				
	Optional (cc)				
	FYI (bcc)				
Scheduler	Click to see invitee status				
Description					

Rebecca- requested feedback on Monsanto's request below.
If there are other items to add please email Susanne.
THANKS!!!

Dear Ms. Cerrelli,

I would appreciate clarification on the first request:

1. Validated detection method protocols and independent lab
validations of the detection methods for CryIA.105
and Cry2Ab2 in
corn need to be submitted.

Monsanto submitted confirmation of a protein-based method that detects
Cry2Ab2 in corn and will allow to separate MON 89034 from all corn
currently on the market to EPA (MRID 46694503) in November 2005. This
method was not yet validated by the third party. This validation will
take place at the end of 2007 when most advanced hybrids will be
available. Previously, such detection method was provided to the Agency

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prior to commercialization of the product.

However, we have developed event-specific DNA-based method that allows to detect MON 89034 in corn grain.

Please, let me know if providing DNA-based method at this time will address the Agency's request.

Thank you very much.

Natalia

-----Original Message-----

From: Cerrelli.Susanne@epamail.epa.gov
[mailto:Cerrelli.Susanne@epamail.epa.gov]
Sent: Monday, April 23, 2007 10:08 AM
To: BOGDANOVA, NATALIA N [AG/1000]
Cc: Mendelsohn.Mike@epamail.epa.gov
Subject: Request for additional data for MON 89034 and MON 89034 x MON88017,

Dear Dr. Natalia Bogdanova,

During our preliminary evaluation of MON 89034 and MON 89034 x MON88017, several items were identified that are needed to complete our evaluation. In order to complete the evaluation process, we wish to notify you of noted deficiencies in Monsanto's submissions.

Monsanto needs to address the following:

1. Validated detection method protocols and independent lab validations of the detection methods for Cry1A.105 and Cry2Ab2 in corn need to be submitted.
2. Plant-produced Cry1A.105 shows both a higher-molecular weight immunoreactive band and lower molecular weight immunoreactive bands in the western blot analysis in addition to the full-length protein. These additional bands appear to be absent in the E. coli-produced protein preparation. Monsanto should address whether these differences are a result of protein purification or whether these different molecular weight proteins are likely present in the plant. Monsanto should also explain why use of the E. coli protein as a surrogate for safety testing is appropriate, given the differences in the protein preparations.
3. Provide the SOPs cited in MRIDs 46951302 (MSL-20145, Study 06-01-50-03), 46951402 (MSL-20311, Study 05-01-39-12),

46951303

(MSL0020479), 46951403 (Study 05-01-39-32, MSL 20285).

4. Discuss determination of equivalence between microbially-produced and plant-produced CryIA.105 using the bioactivity assay (described in MRID 46694604). Were statistics

used? Why was the acceptance criteria determined to be <4 fold

difference between the mean EC50 values in the corn earworm diet-incorporation insect bioassay?

5. Explain the discrepancy in the EC50 definitions given on pages 11 and 8 in MRID 46951405.

Also, we request electronic copies of the following studies: MRIDs 46951403 (Study 05-01-39-32, MSL 20285)?need tables only, 46951404 (MSL-20071)?need figures only, 46951405 (MSL-20132; Study 05-01-39-23), 46951407 (MSL-19931; Study 05-01-62-04)?need figures only, 46951303 (MSL0020479)?need tables only, 46951408 (MSL-19930; Study 05-01-62-03)?need figures only, 46951409 (MSL-19938; Study 05-01-62-05)?need figures only, 46951402 (MSL-20311, Study 05-01-39-12)?need figures only.

Your efforts to address these in a timely manner, would be greatly appreciated. Of course if this is not possible, the PRIA date may need

to be renegotiated. Please note that additional deficiencies may be noted in the future as the evaluations are not completed at this time.

If you have any questions concerning this request, please contact Susanne Cerrelli at 703-308-8077.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077 (w)

Sharlene
Matten/DC/USEPA/US
04/19/2007 03:08 PM

To Janet Andersen/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA
cc Patricia Moe/DC/USEPA/US@EPA, Alan
Reynolds/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Susanne
bcc
Subject SAP needed for IRM issues -- MON 89034 /2 lep toxin
product: Lower Refuge Requirements requested -- no
previous SAP for Bt corn to address this issue

Susanne conducted a MON 89034 team meeting today. She asked me to write up the issues concerning IRM and the need for a SAP meeting.

Monsanto has requested that MON 89034 have significantly lower refuge requirements for their two-toxin (for lep control -- a pyramid) product -- Cry1A.105 + Cry2Ab2. They are requesting a 5% structured non-Bt corn refuge in the Corn Belt (current for 1-tox lep product is 20%) and a 20% structured non-Bt corn refuge in cotton-growing areas (current for 1-tox lep product is 50%). These changes to the IRM requirements for BT corn are significant and a paradigm shift. Monsanto has submitted data to support their request and modeling. These data need to be reviewed. The PRIA date for this action is 6/10/08.

No data have been submitted to support the popcorn use, Monsanto indicated a teleconference we had in February, 2007 that they do not even have a popcorn breeding program. There is no bridging information (IRM, expression, efficacy etc.) to support this use.

However, we received IRM data to support the sweet corn use and bridging arguments for the stacked product of Cry1A.105 + Cry2Ab2 + Cry3Bb1. These data were provided in March, 2007 after a 75-d deficiency letter was issued. I think Monsanto may intend to submit more sweet corn efficacy data needed for the IRM review. We may need to consider a renegotiation of the PRIA date to make up for the time lost - for the sweet corn use.

Sharlene R. Matten, Ph.D.
Biologist
USEPA/OPP/BPPD (7511P)
1200 Pennsylvania Ave., NW
Washington D.C. 20460
703-605-0514

Calendar Entry
Meeting

☒ Notify me
☐ Mark Private ☐ Pencil In

Subject	Brief Team meeting - Monsanto- Mon 89034			Chair	Susanne Cerrelli/DC/U
When	Starts	Thu 04/19/2007	02:00 PM	Where	Location small con
	Ends	Thu 04/19/2007	03:00 PM		Reserved No rooms reserved
				<input type="checkbox"/> Specify a different time zone	
Invitees	Invited	The following invitees have been invited			
	Required (to)	Alan Reynolds/DC/USEPA/US@EPA, John Kough/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Rebecca			
	Optional (cc)	Mika Hunter/DC/USEPA/US@EPA, Zigfridas Valtuzis/DC/USEPA/US@EPA			
Scheduler	Click to see Invitee status				
Description					

Brief meeting to touch base on what is needed by reviewers. - We can keep this to 1/2 an hour if no significant issues identified....

The primary eco -reviews and IRM reviews are done on the original submission. I hope to get this distributed soon.

PROPOSED Agenda:

- 1) Do some of the studies need to be re-distributed?
- 2) Who needs courtesy copies of Data?
- 3) Does Alan want to send the recent IRM response to the contractors?
- 4) Are there issues identified in the primary review that need to be resolved ASAP?
- 5) Are there additional materials needed?
- 6) The petitions for tolerance exemptions was revised- does Rebecca or John want this now?
- 7) Are there other items you need?

- please if you want to add anything to Agenda let me know

SAP → needed for IRM ??

Sydney

June 10, 2008

527-6700

L7L

Oct 24, 2007 → Science review

226



Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314)-694-3143

MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005
PHONE (202) 389-2866
FAX (202) 789-1748
<http://www.monsanto.com>

March 9, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Response to the letter from EPA RE: MON 89034 (CryIA.105 and Cry2Ab2)
Corn and MON 89034 x MON 88017 (CryIA.105, Cry2Ab2, Cry3Bb1) Corn
EPA Petition Numbers 6F7142 and 6F7143
EPA File Symbols: 524-LTA and 524-LTL

Dear Dr. Reilly:

This letter is in response to the Agency's request from January 17, 2007 to address questions pertaining to Monsanto's application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) CryIA.105 and Cry2Ab2 proteins and the genetic material necessary for their production in the corn product MON 89034 and MON 89034 x MON 88017. Some of these questions were clarified at the Monsanto/EPA meeting held on January 25, 2007.

Responses to Agency's questions included in Volume 2 and in a confidential attachment to the Administrative volume. Additional efficacy data is provided as Volume 3. This submission includes the following documents that have been classified as 'A' (non-confidential documents that can be released to the public), 'B' (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers), or 'C' (confidential business information). In addition, pdf and/or Word files are included on a CD-ROM.

Volume	Category	Document	Hard Copy	.pdf or Word file
N/A	A	Cover letter	√	√
N/A	A	Transmittal document	√	√
1	A	Administrative volume	√	
1	C	Confidential statement of formula	√	
1	A	Administrative volume (redacted copy)		√
2	A	Supplemental information	√	√
3	B	Efficacy report	√	

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,



Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto
Monsanto Regulatory Files

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

**REGULATORY ACTION IN SUPPORT OF WHICH
THIS DOCUMENT IS SUBMITTED**

EPA File 524 - LTL and 524-LTA

TRANSMITTAL DATE

March 9, 2007

MONSANTO REFERENCE No.

06-CR-172E-2

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1. Administrative Materials for the Submission of Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

MRID Number Adm

Volume 2. N. N. Bogdanova. 2006. Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

MRID Number 47079402

Volume 3. Headrick et al., 2006. Assessment of the efficacy of insect-protected corn MON 89034, MON 89034 x MON 88017, and MON 89034 x NK603 against major insect pests in the field trials conducted in the U.S. during 2005

MRID Number 47079403

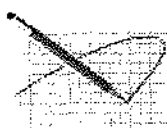
Company Official: Natalia N. Bogdanova 3/9/07

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314) 694-3143

Date

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Director, Regulatory Affairs
(202) 383-2866



Sharlene
Matten/DC/USEPA/US

02/12/2007 12:31 PM

To "BOGDANOVA, NATALIA N [AG/1000]"
<natalia.n.bogdanova@monsanto.com>
"BOGDANOVA, NATALIA N [AG/1000]"
cc <natalia.n.bogdanova@monsanto.com>, Alan
Reynolds/DC/USEPA/US@EPA, "REDING, H KEITH"
bcc

Subject Re: Notes from the phone conversation on February 6, 2007

Natalia -- Thank you for the phone conversation. I have a few corrections to the notes you have provided. See my comments in green below. **Thanks. SRM**

-----"BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>
wrote: -----

To: "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>,
Sharlene Matten/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA
From: "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>
Date: 02/08/2007 03:11PM
cc: "REDING, H KEITH [AG/1000]" <h.keith.reding@monsanto.com>, "SCHNEIDER,
RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>, "LAHMAN, LINDA K
[AG/1000]" <linda.k.lahman@monsanto.com>, Susanne Cerrelli/DC/USEPA/US@EPA,
Mike Mendelsohn/DC/USEPA/US@EPA
Subject: Notes from the phone conversation on February 6, 2007

Sharlene,

Thank you for a very informative conversation yesterday. This message is to summarize the key points of the discussion to make sure we are in agreement.

In order to maintain sweet corn in Monsanto's application to register MON 89034 and MON 89034 x MON 88017 the following plan was proposed:

Sweet corn

- In order to obtain registration for sweet and popcorn a limited dataset should be provided.
- Leaf expression data for MON 89034 that will be provided by Monsanto should be sufficient to retain sweet corn in the application. EPA agrees we can collect expression data from the leaf of flowering MON 89034 sweet corn currently being grown in Hawaii. The leaf tissue is currently being harvested and the data is expected to be submitted to EPA in March 2007.
- Limited efficacy data (leaf disk insect bioassay using ECB and FAW) will be also collected and provided to the Agency within similar timeframe.
- If necessary, FAW and ECB efficacy can be confirmed in field efficacy trials at a single location in 2007-08.

Comments on bullets 2-4:

I didn't say just leaf expression data were adequate. What I said was that a leaf disc bioassay would be the first step one would need to support the sweet corn use. I then said that Monsanto would need both field efficacy data and field expression data and

that this could be done using the MON 89034 sweet corn currently being grown in Hawaii and such data would be submitted in Fall 2007. One would have to explain how these data would be representative of other mainland growing areas for sweet corn. In addition to leaf expression, one needs pollen expression, stalk expression, and ear expression for pests such as corn earworm, fall armyworm, and European corn borer (although I would expect this pest to be of lesser importance for sweet corn given where it is grown in the U.S.) at the appropriate plant developmental stages.

- The timing of actions for sweet corn should not affect field corn registration PRIA date unless that data is submitted later than January 2008. Sharlene indicated that how the data submitted in March 2007 and later in 2007 to support the sweet corn use (insect resistance management issues) would affect the PRIA date needs to be discussed with Susanne Cerrelli and Mike Mendelsohn as well as any administrative or regulatory question.

Popcorn

- Popcorn varieties of MON 89034 have not been developed yet.
- Both field efficacy and expression data would need to be submitted at some future date to address insect resistance management should MON 89034 be registered for popcorn use.
- Monsanto prefers that popcorn be retained in the registration request but as a condition of the registration, expression and efficacy data must be provided before MON 89034 can be commercialized in popcorn. Sharlene pointed out that without any data to support the popcorn use that this would be unlikely. She indicated that this issue should be discussed further with the RALs, Susanne Cerrelli and Mike Mendelsohn.

Please, let me know if we understood each other correctly. Thank you very much for your time and attention to MON 89034.

Best regards,

Natalia

-----Original Message-----

From: BOGDANOVA, NATALIA N [AG/1000]
Sent: Tuesday, February 06, 2007 11:19 AM
To: 'matten.sharlene@epa.gov'
Cc: REDING, H KEITH [AG/1000]; SCHNEIDER, RUSSELL P [AG/1920]
Subject: Information for today's discussion

Sharlene,

Here is the information we would like to discuss in the call this afternoon.

EPA Discussion Points for MON 89034 Sweet Corn

In a January 17, 2007 letter to Monsanto, EPA requested expression data on sweet corn and popcorn to perform an IRM assessment.

- We can provide expression data on MON 89034 sweet corn by mid-March 2007. We currently have MON 89034 sweet corn growing in Hawaii. The plants are at the flowering stage. We plan to take leaf samples from up to 10 plants and determine the dry weight expression of Cry1A.105 and Cry2Ab2.
- Field corn, popcorn and sweet corn all belong to the taxonomic

group *Zea mays* subsp. *mays* ; therefore, we expected that the expression level for sweet corn and popcorn to be in the range seen for field corn.

- The proposed IRM plan for sweet corn requires no structured refuge but rather destruction of the stalks after harvest, before the larvae can mature. Therefore, the expression level of the proteins should have no impact on the overall IRM plan.
- MON 89034 has not been bred into popcorn at this time. However, we would like popcorn included on the label to allow for future use in popcorn.

Look forward to talk to you.

Natalia

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.,
St. Louis, MO 63167

Tel. (314) 694-3143

FAX (314) 694-3080

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"BOGDANOVA,
NATALIA N [AG/1000]"
<natalia.n.bogdanova
@monsanto.com>

02/08/2007 03:11 PM

"BOGDANOVA, NATALIA N [AG/1000]"
To <natalia.n.bogdanova@monsanto.com>, Sharlene
Matten/DC/USEPA/US@EPA, Alan
"REDING, H KEITH [AG/1000]"
cc <h.keith.reding@monsanto.com>, "SCHNEIDER, RUSSELL
P [AG/1920]" <russell.p.schneider@monsanto.com>,
bcc

Subject: Notes from the phone conversation on February 6, 2007

Sharlene,

Thank you for a very informative conversation yesterday. This message is to summarize the key points of the discussion to make sure we are in agreement.

In order to maintain sweet corn in Monsanto's application to register MON 89034 and MON 89034 x MON 88017 the following plan was proposed:

Sweet corn

- In order to obtain registration for sweet and popcorn a limited dataset should be provided.
- Leaf expression data for MON 89034 that will be provided by Monsanto should be sufficient to retain sweet corn in the application. EPA agrees we can collect expression data from the leaf of flowering MON 89034 sweet corn currently being grown in Hawaii. The leaf tissue is currently being harvested and the data is expected to be submitted to EPA in March 2007.
- Limited efficacy data (leaf disk insect bioassay using ECB and FAW) will be also collected and provided to the Agency within similar timeframe.
- If necessary, FAW and ECB efficacy can be confirmed in field efficacy trials at a single location in 2007-08.
- The timing of actions for sweet corn should not affect field corn registration PRIA date unless that data is submitted later than January 2008.
- All administrative questions should be further addressed to Mike Mendelsohn and Susanne Cerelli.

Popcorn

- Popcorn varieties of MON 89034 have not been developed yet.
- The same data requirement will apply to popcorn and can be submitted at a later date
- Monsanto prefers that popcorn be retained in the registration request but as a condition of the registration, expression and efficacy data must be provided before MON 89034 can be commercialized in popcorn.

Please, let me know if we understood each other correctly. Thank you very much for your time and attention to MON 89034.

Best regards,

Natalia

-----Original Message-----

From: BOGOANOVA, NATALIA N [AG/1000]
Sent: Tuesday, February 06, 2007 11:19 AM
To: 'matten.sharlene@epa.gov'
Cc: REOING, H KEITH [AG/1000]; SCHNEIDER, RUSSELL P [AG/1920]
Subject: Information for today's discussion

Sharlene,

Here is the information we would like to discuss in the call this afternoon.

EPA Discussion Points for MON 89034 Sweet Corn

In a January 17, 2007 letter to Monsanto, EPA requested expression data on sweet corn and popcorn to perform an IRM assessment.

- We can provide expression data on MON 89034 sweet corn by mid-March 2007. We currently have MON 89034 sweet corn growing in Hawaii. The plants are at the flowering stage. We plan to take leaf samples from up to 10 plants and determine the dry weight expression of Cry1A.105 and Cry2Ab2.
- Field corn, popcorn and sweet corn all belong to the taxonomic group *Zea mays* subsp. *mays* ; therefore, we expected that the expression level for sweet corn and popcorn to be in the range seen for field corn.
- The proposed IRM plan for sweet corn requires no structured refuge but rather destruction of the stalks after harvest, before the larvae can mature. Therefore, the expression level of the proteins should have no impact on the overall IRM plan.
- MON 89034 has not been bred into popcorn at this time. However, we would like popcorn included on the label to allow for future use in popcorn.

Look forward to talk to you.

Natalia

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.,
St. Louis, MO 63167

Tel. (314) 694-3143
FAX (314) 694-3080

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No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B), or (C).

Company: Monsanto Company

Natalia N. Bogdanova
Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

[illegible]

GLP COMPLIANCE STATEMENT

This volume provides the administrative materials for the submission of supplemental information to address EPA questions regarding applications 524-LTL and 524-LTA to register insect-protected corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300) and therefore were not developed in compliance with 40 CFR Part 160.

Natalia N. Bogdanova

3/09/07

Submitter

Date

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

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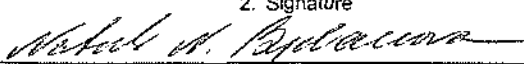
Administrative Materials

Application to Register (Form 8570-1)

Confidential Statement of Formula (Form 8570-4)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

 <div style="display: inline-block; vertical-align: middle;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number File Symbol 524-LTL and 524-LTA		2. EPA Product Manager Sheryl Reilly	
Company/Product (Name) MON 89034 and MON 89034 x MON 88017		PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section – II			
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other – Explain below.	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Submission of Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)			
Section – III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <div style="text-align: center; font-weight: bold;">Various</div>	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section – IV			
f. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Russell P. Schneider		Title Director, Regulatory Affairs	
Telephone No. (Include Area Code) (202) 383-2866		6. Date Application Received <div style="text-align: center; font-weight: bold; font-size: 1.2em;">(Stamped)</div>	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 		3. Title Regulatory Affairs Manager	
4. Typed Name Natalia N. Bogdanova Tel. (314) 694-3143		5. Date March 9, 2007	

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CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167 Tel. (314) 694-3143	EPA Registration Number / File Symbol: 524-LTL and 524-LTA
Active Ingredient(s) and/or representative test compound(s): Bacillus thuringiensis Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in corn	Date: March 9, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: > Lepidopteran-Protected Corn (MON 89034) > Lepidopteran and Coleopteran protected and glyphosate tolerant corn (MON 89034 x MON 88017)

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by

Section III: CERTIFICATION


I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

☒ I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date March 9, 2007	Typed or Printed Name and Title Natalia N. Bogdanova, D.V.M., Regulatory Affairs Manager
--	-----------------------	--

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0040.

(244)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: March 9, 2007

EPA Reg. No./File Symbol: 524-LTL and 524-LTA

Page 1 of 2

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 and MON 89034 x MON 88017

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material (vector PV-ZMIR245) necessary for their production in MON 89034 corn (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	N.N. Bogdanova, 2007. Administrative Materials for Submission of Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)		Monsanto Company	OWN	This Submission
	N. N. Bogdanova, 2006. Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)		Monsanto Company	OWN	This Submission
	Headrick et al., 2006. Assessment of the efficacy of insect-protected corn MON 89034, MON 89034 x MON 88017, and MON 89034 x NK603 against major insect pests in the field trials conducted in the U.S. during 2005		Monsanto Company	OWN	This Submission
Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date March 9, 2007	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 9, 2007

EPA Reg. No./File Symbol: 524-LTL
and 524-LTA

Page 1 of 1

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 and MON 89034 x MON 88017

Ingredient: *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 corn (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date March 9, 2007

MON 89034

Corn Borer -Protected Corn (OECD Unique Identifier: MON-89034-3)

This product is effective in controlling damage caused by corn borer, fall armyworm, corn earworm and corn rootworm larval feeding on stalks, leaves, and ears of field corn, popcorn, and sweet corn.

Active Ingredient:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (Vector ZMIR 245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3).....0.0031 - 0.0084%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (Vector ZMIR 245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3).....0.0030 - 0.0057%

Other Ingredients: none

Percentage (wt/wt) on a dry weight basis whole plant (forage).

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-LTL

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. The following information regarding commercial production must be included in the MON 89034 corn Technology Use Guide (TUG) and the Insect Resistance Management (IRM) Guide.

MON 89034 protects corn crops from leaf, stalk, and ear damage caused by corn borers. In order to minimize the risk of these pests developing resistance to MON 89034 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

INSECT RESISTANCE MANAGEMENT

Growers of MON 89034 must adhere to all of the following refuge requirements.

Growers in counties in which no cotton is grown (e.g., counties in the northern corn belt) must plant a minimum of 5% non-lepidopteran-protected corn as a structured refuge. Growers in counties in which cotton is grown must plant a minimum of 20% non-lepidopteran-protected corn as a structured refuge.

The refuge must be placed within ½ mile (within ¼ mile preferred) of the MON 89034 field. When planting the refuge in strips, the strips must be at least four rows wide.

Insecticide treatments for control of European corn borer, southwestern corn borer and corn earworm may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial Bt insecticides cannot be applied to the refuge acres.

These refuge requirements will not apply to operations engaged in the propagation of inbred and hybrid seed corn.

CORN INSECTS CONTROLLED OR SUPPRESSED

MON 89034 field corn, sweet corn and popcorn produce the *Bt* proteins, Cry1A.I05 and Cry2Ab2, that control or suppress the following lepidopteran and coleopteran insects:

European corn borer (*Ostrinia nubilalis*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
Southwestern corn borer (*Diatrea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Sugarcane borer (*Diatraea saccharalis*)

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. Patents: 38-21(52905); 38-21 (53618).

MON 89034 × MON 88017

Corn Borer and Rootworm-Protected Corn (OECD Unique Identifier: MON-89034-3 × MON-88017-3)

This product is effective in controlling damage caused by corn borer, fall armyworm, corn earworm and corn rootworm larval feeding on stalks, leaves, ears, and roots of field corn, popcorn and sweet corn.

Active Ingredient:

Bacillus thuringiensis CryIA.105 protein and the genetic material necessary for its production (Vector ZMIR 245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3).....0.0031 - 0.0084%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (Vector ZMIR 245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3).....0.0030 - 0.0057%

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88017-3).....0.0037 - 0.0070%

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (Vector ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88017-3).....0.0042 - 0.0069%

Percentage (wt/wt) on a dry weight basis whole plant (forage).

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-LTA

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. The following information regarding commercial production must be included in the MON 88017 corn Technology Use Guide (TUG) and Insect Resistance Management (IRM) Guide.

MON 89034 × MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × MON 88017 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

INSECT RESISTANCE MANAGEMENT

For MON 89034 × MON 88017 corn grown in non-cotton growing regions of the United States, two options for deployment of the refuge are available to growers. Growers in counties in which no cotton is grown (e.g., counties in the northern corn belt) must plant a minimum of 5% non-lepidopteran-protected corn as a structured refuge. Growers in counties in which cotton is grown must plant a minimum of 20% non-lepidopteran-protected corn as a structured refuge.

Growers may choose to plant a common refuge for both corn borer and corn rootworm pests, or they may choose to plant separate corn borer and corn rootworm refuges. For growers who do not typically apply insecticides for control of corn borers, the common refuge option may be appropriate. In regions where corn borer infestations are high, growers may benefit from planting separate corn borer and corn rootworm refuges. This option is appropriate when corn borer infestations are expected to exceed economic thresholds. The benefit of a separate refuge allows the grower to manage corn borer in both the corn rootworm refuge (by planting corn borer-protected corn in this refuge) and corn borer refuge (by applying conventional insecticides) without having to spray the entire MON 89034 × MON 88017 field (Common Refuge Option: Refuge Management).

1. Common Refuge Option

- a) **Refuge Size** - Growers must plant a minimum of 20% non-Bt corn as a structured refuge. This refuge size applies throughout the US.
- b) **Refuge Placement and Configuration** - The refuge must be placed within or adjacent to the MON 89034 × MON 88017 field. Refuge deployment options include continuous blocks adjacent to the MON 89034 × MON 88017 field, continuous blocks within the MON 89034 × MON 88017 field, strips around the MON 89034 × MON 88017 field, or strips within the MON 89034 × MON 88017 field. When planting the refuge in strips, the strips must be at least four rows wide.
- c) **Refuge Management** - The refuge and MON 89034 × MON 88017 acres should be managed under comparable agronomic regimes. In MON 89034 × MON 88017 fields where corn is cropped continuously, refuge acres should be planted in a continuous cropping regime. The refuge may be placed on first-year corn

acres only if the MON 89034 × MON 88017 corn is planted on first-year corn acres. Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt insecticide to control late season pests such as corn borer or corn rootworm adults. However, if growers opt to treat the refuge while adult corn rootworm are present, then the MON 89034 × MON 88017 acres must be treated in a like manner. Microbial Bt insecticides cannot be applied to the refuge acres.

2. Separate Refuge Option

The Corn Rootworm Refuge:

- a) **Refuge Size** – Growers must plant a minimum of 20% non-corn rootworm-protected corn (i.e., corn not containing Cry3Bb1 protein) as a structured refuge. This refuge size applies throughout the US. This refuge should be planted with corn borer-protected corn (e.g., MON 89034). A separate corn borer refuge also must be established (see Corn Borer Refuge below).
- b) **Refuge Placement and Configuration** - The refuge must be placed within or adjacent to the MON 89034 × MON 88017 field. Refuge deployment options include continuous blocks adjacent to the MON 89034 × MON 88017 field, continuous blocks within the MON 89034 × MON 88017 field, strips around the MON 89034 × MON 88017 field, or strips within the MON 89034 × MON 88017 field. When planting the refuge in strips, the strips must be at least four rows wide.
- c) **Refuge Management** - The refuge and MON 89034 × MON 88017 acres should be managed under comparable agronomic regimes. In MON 89034 × MON 88017 fields where corn is cropped continuously, refuge acres should be planted in a continuous cropping regime. The refuge may be placed on first-year corn acres only if the MON 89034 × MON 88017 corn is planted on first-year corn acres. Growers have the option of applying conventional insecticides or seed treatments to the corn refuge for control of corn rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt insecticide to control late season pests. However, if growers opt to treat the refuge while adult corn rootworm are present then the MON 89034 × MON 88017 acres must be treated in a like manner. Microbial Bt insecticides cannot be applied to the refuge acres.

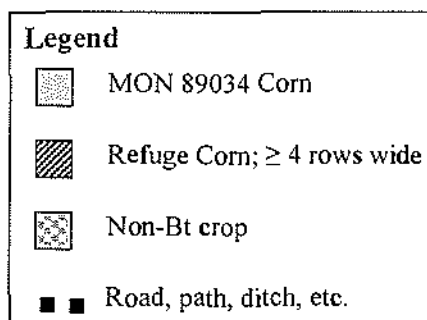
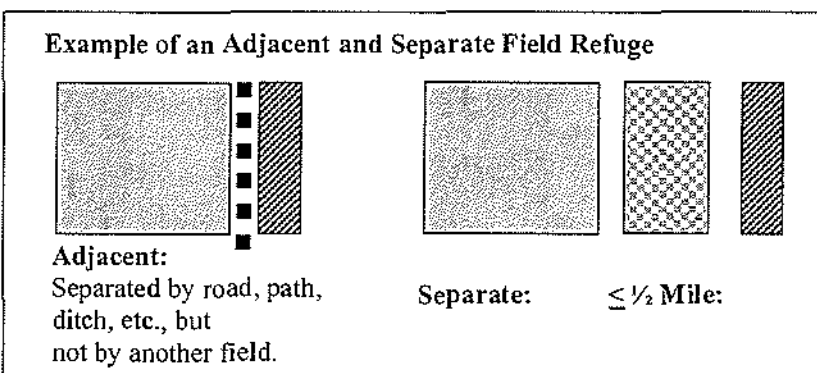
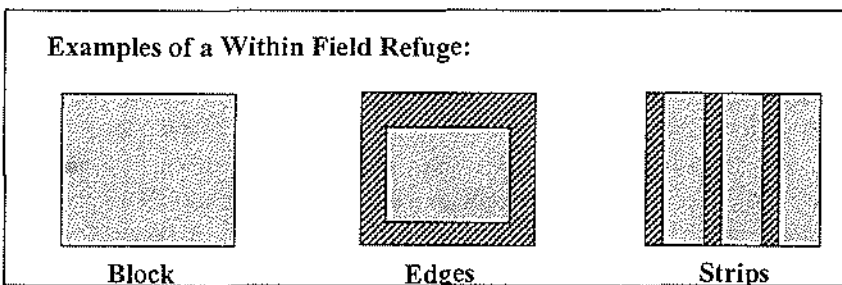
The Corn Borer Refuge:

- a) **Refuge Size** - Growers in counties in which no cotton is grown (e.g., counties in the northern corn belt) must plant a minimum of 5% non-Bt corn as a structured refuge. Growers in counties in which cotton is grown must plant a minimum of 20% non-Bt corn as a structured refuge.
- b) **Refuge Placement and Configuration** - The refuge must be placed within ½ mile (within ¼ mile preferred) of the MON 89034 × MON 88017 and corn rootworm refuge fields. When planting the refuge in strips, the strips must be at least four rows wide.

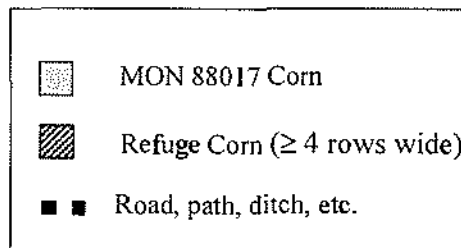
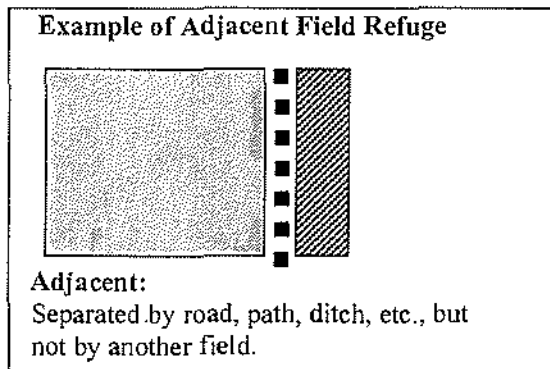
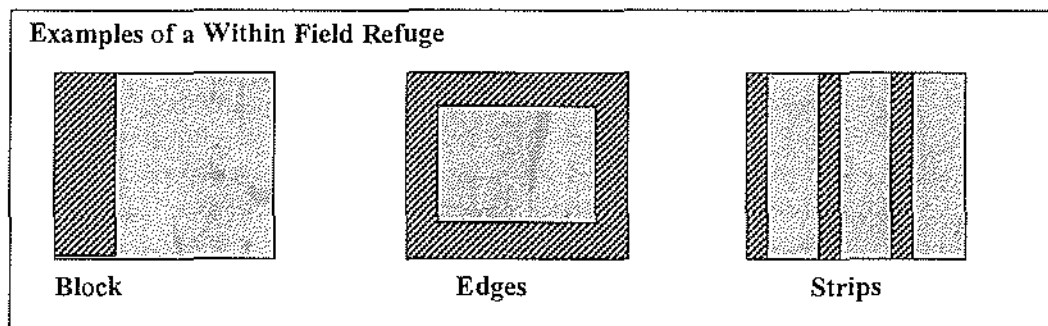
- c) Refuge Management - Growers have the option of applying conventional insecticides or seed treatments to the refuge for control of corn rootworm larvae. Insecticide treatments for control of European corn borer, southwestern corn borer and corn earworm may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial Bt insecticides cannot be applied to the refuge acres.

These refuge requirements will not apply to operations engaged in the propagation of inbred and hybrid seed corn.

MON 89034 corn refuge placement and configuration options:

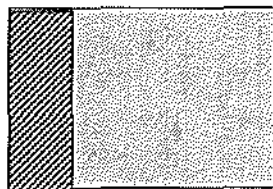


MON 88017 corn refuge placement and configuration options:

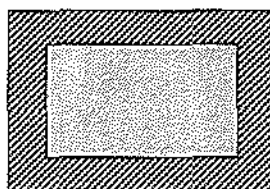


MON 89034 × MON 88017 corn: Common refuge placement and configuration options for MON 88017 and MON 89034

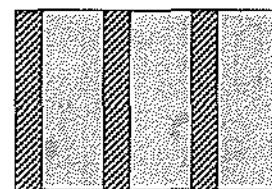
Examples of Within Field Common Refuge for MON 88017 and MON 89034



Block

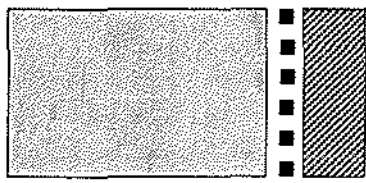


Edges



Strips




Example of Adjacent Field Common Refuge for MON 88017 and MON 89034



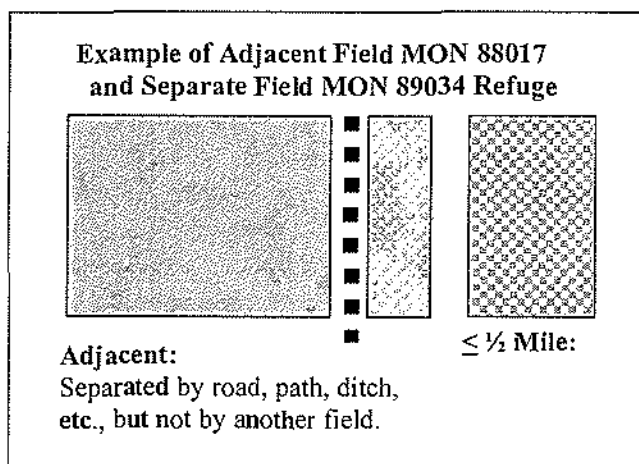
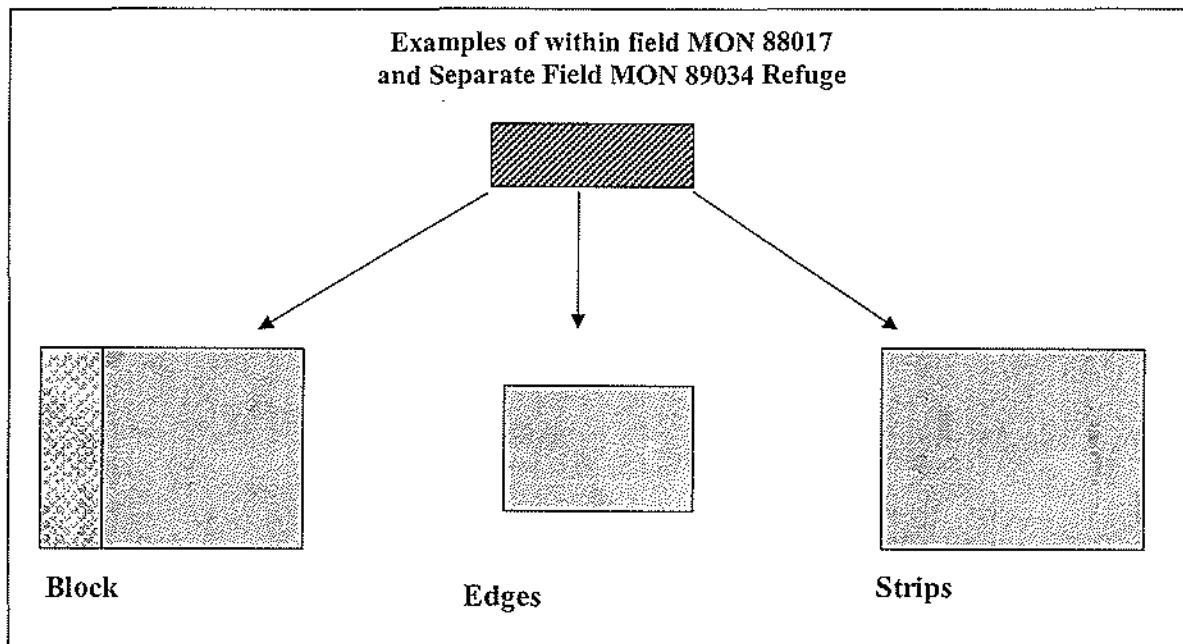
Adjacent:

Separated by road, path, ditch, etc., but not by another field.






Legend

-  MON 89034 × MON 88017 Corn
-  Refuge Corn (≥ 4 rows wide)
-  Road, path, ditch, etc.

**MON 89034 × MON 88017: Separate refuge placement and configuration options
for MON 88017 and MON 89034**



Legend

-  MON 89034 × MON
-  MON 88017 Refuge – MON 89034
(≥ 4 rows wide)
-  MON 89034 Refuge (≥ 4 rows wide)
-  Non-corn crop
-  Road, path, ditch, etc.

CORN INSECTS CONTROLLED OR SUPPRESSED

MON 89034 field corn, popcorn, and sweet corn produce the *Bt* proteins, Cry1A.105, Cry2Ab2, and Cry3Bb1, that control or suppress the following lepidopteran and coleopteran insects:

- European corn borer (*Ostrinia nubilalis*)
- Corn earworm (*Helicoverpa zea*)
- Fall armyworm (*Spodoptera frugiperda*)
- Southwestern corn borer (*Diatrea grandiosella*)
- Southern cornstalk borer (*Diatraea crambidoides*)
- Sugarcane borer (*Diatrea saccharalis*)
- Western corn rootworm (*Diabrotica virgifera virgifera*)
- Northern corn rootworm (*Diabrotica barberi*)
- Mexican corn rootworm (*Diabrotica virgifera zea*)

MON 89034 × MON 88017 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. Patents: 38-21(52905); 38-21 (53618); 4,940,835; 5,164,316; 5,188,642; 5,196,525; 5,322,938; 5,359,142; 5,633,435; 5,641,876; 5,717,084; 5,728,925; 5,804,425; and 6,501,009.

MB

Title

Administrative Materials for the Submission of Supplemental Information to Address
EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-
protected Corn MON 89034 and MON 89034 x MON 88017
(MRID 46951400 and 46951300)

CONFIDENTIAL ATTACHMENT

Author

Natalia N. Bogdanova, D.V.M.

Registrant Submission Date

March 9, 2007

Registrant Submitting

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

Registrant Document No.

04-CR-172E-2

Volume 1 of 3

EPA Registration File No. 524-576 Vol. # 1.

Page _____ is not included in this copy.

Pages 258 through 260 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

X The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-client communication.

_____ Claimed confidential by submitter upon submission to the Agency.

_____ Third party confidential business information.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

MONSANTO



Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314) 694-1143

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

February 5, 2007

Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly

Subject: Memorandum of Understanding; EPA Petition Numbers 6F7142 and 6F7143;
EPA File Symbols: 524-LTA and 524-LTL

Dear Dr. Reilly,

I would like to thank you and the other members of your team for meeting with Monsanto on January 25, 2007 to address reviewer's questions regarding the IRM plan proposed for Monsanto's second generation lepidopteran-protected corn product MON 89034 (EPA File Symbol 524-LTL).

The summary and conclusions from our conversation are provided below. Please add to or revise them if your understanding of the meeting differs.

EPA Participants:

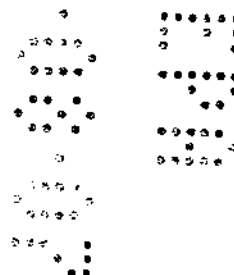
Sheryl Reilly, Sharlene Matten, Mike Mendelsohn, Tess Milofski, Alan Reynolds,
Susanne Cerelli, Patricia Moe

Monsanto Company Participants:

Russell Schneider, Linda Lahman, Graham Head, Natalia Bogdanova

The discussion focused around the January 17, 2007 letter from EPA that outlined general questions and requests for information, and specific questions related to the proposed IRM plan for MON 89034. Graham Head presented an outline of the IRM plan and discussed the underlying data. Questions listed below (in italics) are quoted from the letter of January 17, 2007.

2 SUBMISSIONS
included



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General questions:

1. *The insect resistance management (IRM) package for MON 89034 x MON 88017 is deficient. There is no bridging rationale provided that links the dose and efficacy of the stacked product to that of each single gene product for each target pest as justification for the proposed IRM plan for the stacked product.*

Monsanto will provide a bridging rationale that includes expression and efficacy data against target pests by comparing single and combined trait products.

2. *Expression data are necessary for popcorn and sweet corn in order to perform the IRM assessment.*

For the IRM assessment of MON 89034 sweet corn and popcorn, the Agency requested limited expression and efficacy data to bridge with data obtained for field corn. Information regarding the similarity of sweet corn to field corn and relevance to IRM would not be sufficient for the existing EPA framework. Information developed for sweet corn can be applied to popcorn. Monsanto will follow up on the request in a response letter.

3. *The tolerance petitions requests that 40 CFR Part 180 be amended to remove time limitation for the temporary exemptions from the requirement of a tolerance. These need to be modified so that you request to amend 40 CFR Part 174.453 and 174.454 to make them permanent exemptions from the requirement of a tolerance. Temporary tolerance exemptions not only have time limitations, but are linked to specific experimental use permits.*

As directed by EPA Monsanto will re-submit petitions to amend temporary tolerances for the Cry1A.105 and Cry2Ab2 proteins with requests for permanent tolerances to support the registration request for MON 89034. In addition, Monsanto will extend the request to include all crops and commodities based on confirmation from EPA. This action has no impact on timelines for MON 89034.

4. *IRM-specific questions:*

- a. What are the relative contributions of each toxin (i.e., dose of each toxin and selection)? Explain "dose" studies and your assumptions about dominance and inheritance of resistance.*
- b. How is Roush's model used for predicting resistance (relative contribution of each toxin) to ECB? What are the assumptions?*
- c. What information relative to each toxin, is being fitted to the Monsanto revised bollworm model?*

Graham Head addressed the above questions in the presentation. Monsanto will provide additional clarification on the methods used to assess the level of control (dose) conferred by each of the Cry1A.105 and Cry2Ab2 components in MON 89034, and how these data

Dr. S. Reilly
February 5, 2007

Page 3 of 3

are incorporated into mathematical models for the different target pests. However, no additional data should be necessary. Monsanto will also provide the PowerPoint presentation that was used at the meeting.

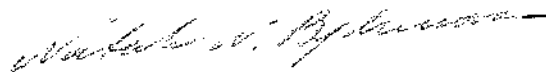
The following topics were also discussed:

- Benefits data and content of a Public Interest Document (PID) that Monsanto provides to EPA for each product were discussed. Sharlene Matten provided a handout with guidance on information the Agency would need, including the activity of our product on fall armyworm. Monsanto plans on submitting MON 89034 and MON 89034 x MON 88017 PIDs later this year.
- The Agency indicated that it was helpful to the reviewer to have relevant background data such as expression in the IRM volume. Monsanto pointed out that Volume 2 of the submission contains a summary of the submission and can be used as reference for each study if necessary.

Based on this conversation, Monsanto will provide responses to the questions posed in the EPA letter of January 17 within the next two weeks.

We would appreciate an affirmation of EPA's agreement with these notes. If you would like to discuss this memorandum of understanding, please contact Dr. Russ Schneider at (202) 383-2866 or me at (314) 694-3143.

Sincerely,



Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

cc: Russ Schneider/Monsanto
Monsanto Regulatory Files

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EPA/Monsanto meeting 5, 2007

HPC

The Second Generation Lepidopteran-protected Corn Product MON 89034: IRM Considerations

(Vector PV-ZMIR245)

Dr. Natalia Bogdanova
Dr. Graham Head

Monsanto Company

Agenda

- **Product Overview and Status**
- **IRM considerations for MON 89034**
- **Discussion**

Second Generation Lepidopteran- protected Corn Product Description

MON 89034

- Vector PV-ZMIR245
- Active Ingredients – Cry2Ab2 and Cry1A.105
- Inert Ingredient – None

MON 89034 x MON 88017

- Produced by conventional breeding of MON 89034 and MON 88017
- Vectors PV-ZMIR245 and PV-ZMIR39
- Active Ingredients – Cry2Ab2 and Cry1A.105, and Cry3Bb1
- Inert Ingredient – CP4 EPSPS

Product Concept

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- ✓ **Increased spectrum of activity against lepidopteran insect pests compared to MON 810**
 - Ostrinia* – ECB
 - Diatrea* – SWCB, SCB
 - Additional activity:**
 - Spodoptera* – FAW
 - Helicoverpa* - CEW
- ✓ **IRM benefit: produce two Bt proteins, Cry1A.105 and Cry2Ab2**
- ✓ **In addition:**
 - **Combination with MON 88017 offers CRW protection and herbicide tolerance**

8/12

Current status

- ✓ Temporary tolerance exemptions for Cry1A.105 and Cry2Ab2 protein granted in June 2006
- ✓ Field testing ongoing under an EUP (524-EUP-97)
- ✓ Applications to register MON 89034 and MON 89034 x MON 88017 submitted in September 2006
- ✓ Petitions to amend temporary tolerance exemptions for Cry1A.105 and Cry2Ab2 to remove time limitations submitted in November 2006

Insect Resistance Management for MON 89034

Overview

- The dual effective dose concept
- MON 89034 as a dual effective dose product
 - Low likelihood of cross-resistance between Cry1A.105 and Cry2Ab2
 - High level of control of key target pests
- IRM considerations

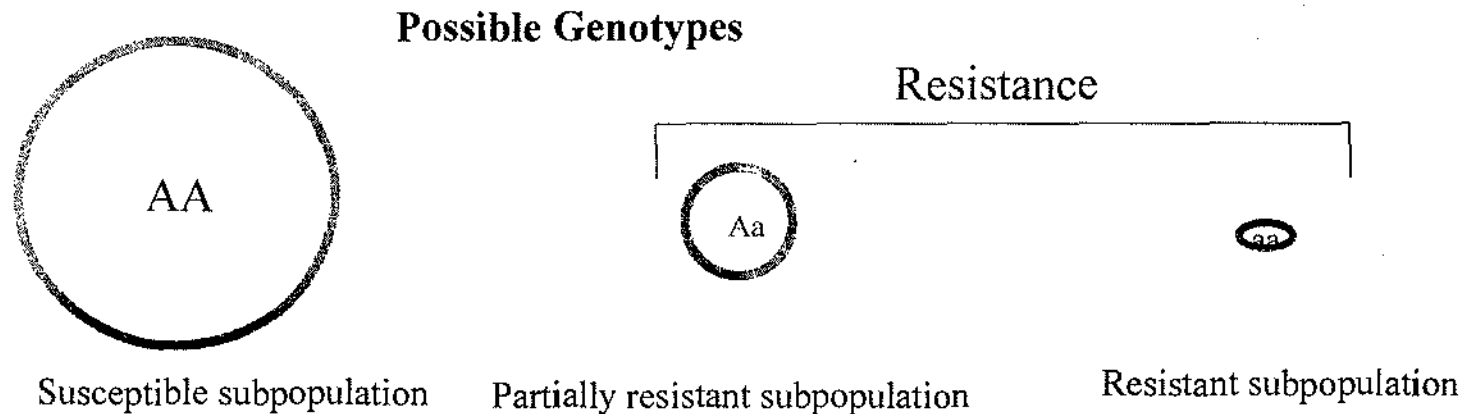
Dual Effective Dose Concept

- For a product with two Bt proteins, the IRM benefit is greatest when Bts are not cross-resistant and each gives at least 95% control of target pests = Dual Effective Dose
 - Value is considerable if at least one protein gives >95% control
- Dual Effective Dose (DED) against key target pests:
 - Demonstrate high level of control by each protein
 - Demonstrate low probability of cross-resistance

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With one ~~Pt~~ protein:

Eliminate most of the resistant alleles from the population using a high dose

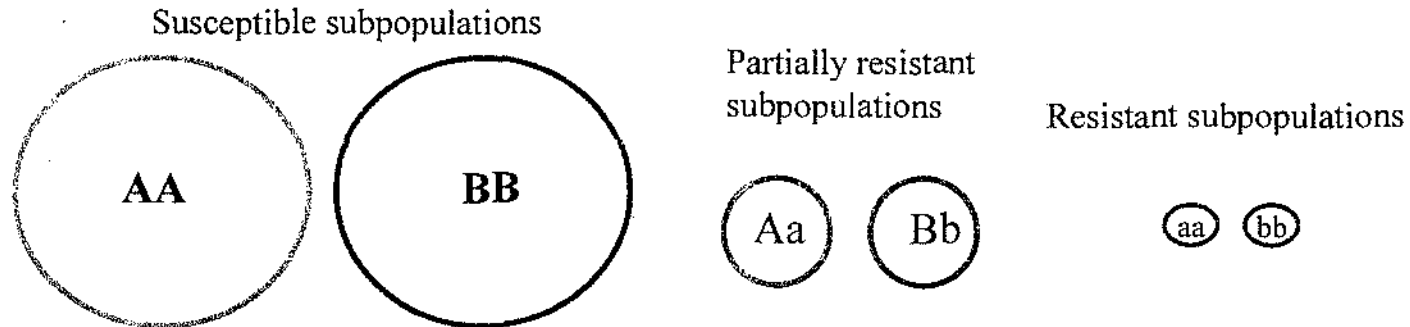


The most effective way to eliminate resistant alleles is killing partially resistant insects because these Aa insects are much more common than the fully resistant aa insects.

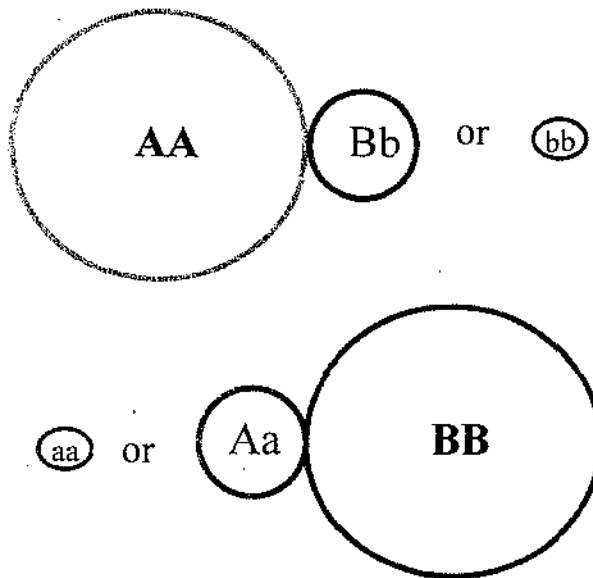
High dose is the concentration needed to kill the susceptible and partially resistant insects.

With two B proteins:

Eliminate most of the resistant alleles from the population using an effective dose of each protein

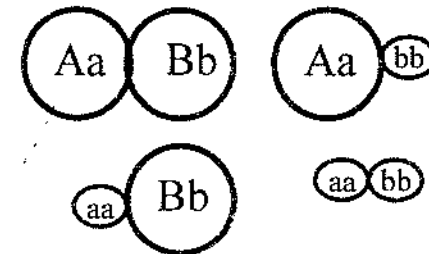


We assume that the two resistant loci assort independently.



IRM goal is **an effective dose of both proteins** to kill insects **susceptible** to either protein. This is because the insects we need to control in this case are those resistant or partly resistant to one protein but susceptible to the other protein (AAbb, AABb, AaBB and aaBB).

Other resistant phenotypes are rarer (AaBb, Aabb, aaBb and aabb) and are less important.



With two Bt proteins:

(assume allele frequency = 0.002)

	AB	Ab	aB	ab
AB	AABB 99.2	AABb 0.20	AbBB 0.20	AaBb 0.0004
Ab	AABb 0.20	AAbb 0.0098	AaBb 0.0004	Aabb 0.0000008
aB	AaBB 0.20	AaBb 0.0004	aaBB 0.0004	aaBb 0.0000008
ab	AaBb 0.0004	Aabb 0.0000008	aaBb 0.0000008	Aabb 0.000000016

Compared with one protein, where Aa = 0.4% and aa = 0.0004%

Dual Effective Use Criteria

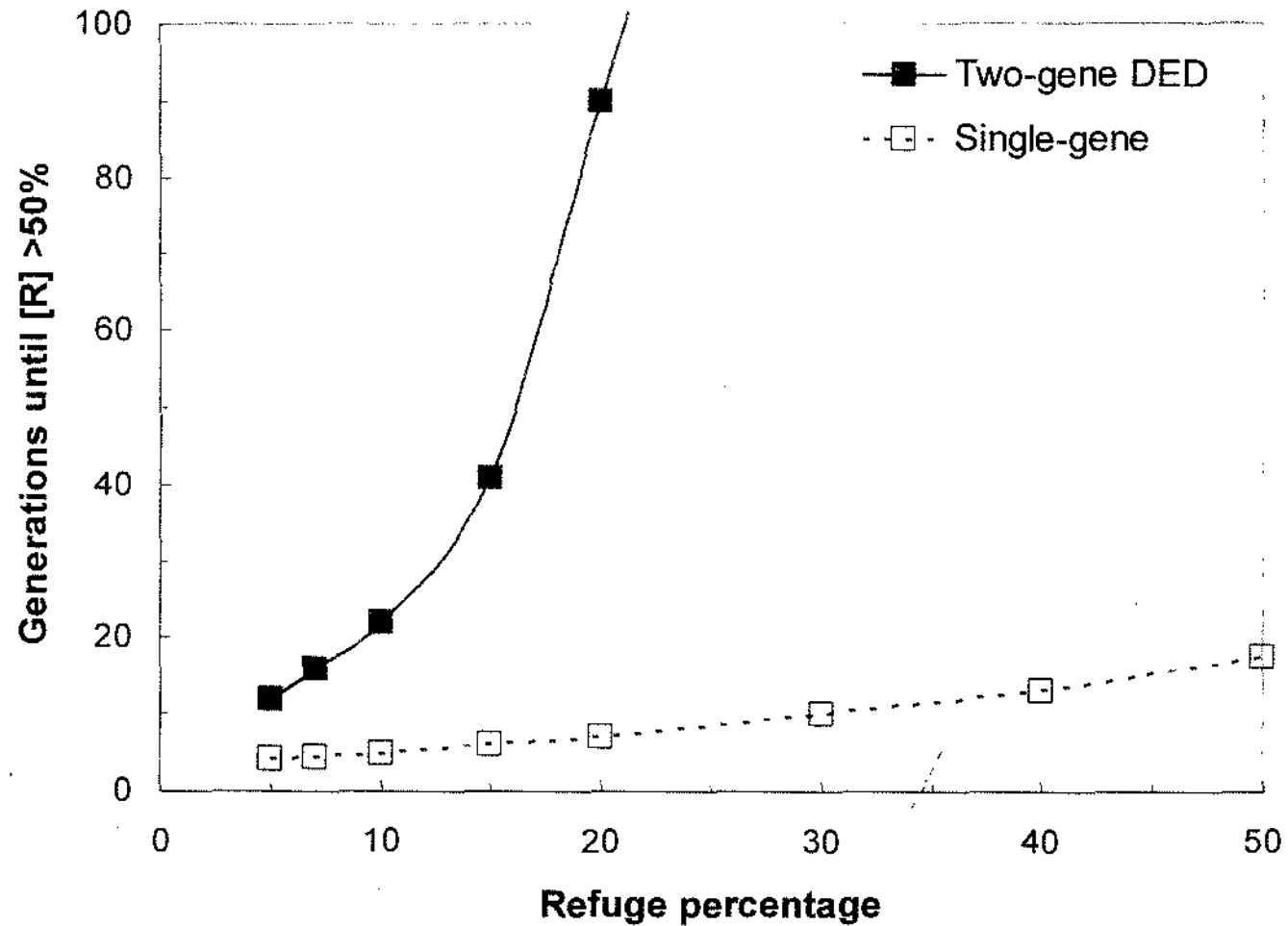
- Modeling by Roush based on diamondback moth (DBM) genetics
 - Resistance is partially recessive (heterozygotes show some resistance)
- Little or no cross-resistance and 95% control of susceptible insects is desired
 - If resistance is more recessive, then Dual Effective Dose products are even more durable
- This modeling is the basis for the IRM decisions made for Bt cotton in Australia

Durability of DED

Durability of Single

5% Refuge \geq
20% Refuge

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(27)

Low Likelihood of Cross-resistance Between Cry1A and Cry2Ab2 (comparable to the previous case)

- ❑ Substantial sequence and structural differences suggest differences in mode of action
- ❑ Differences in binding receptors and kinetics of binding
- ❑ No significant cross-resistance of Cry2Ab2-resistant *Helicoverpa armigera* to Cry1A.105

No Significant Impact of Prior Use of Cry1Ab-expressing

MON 89034

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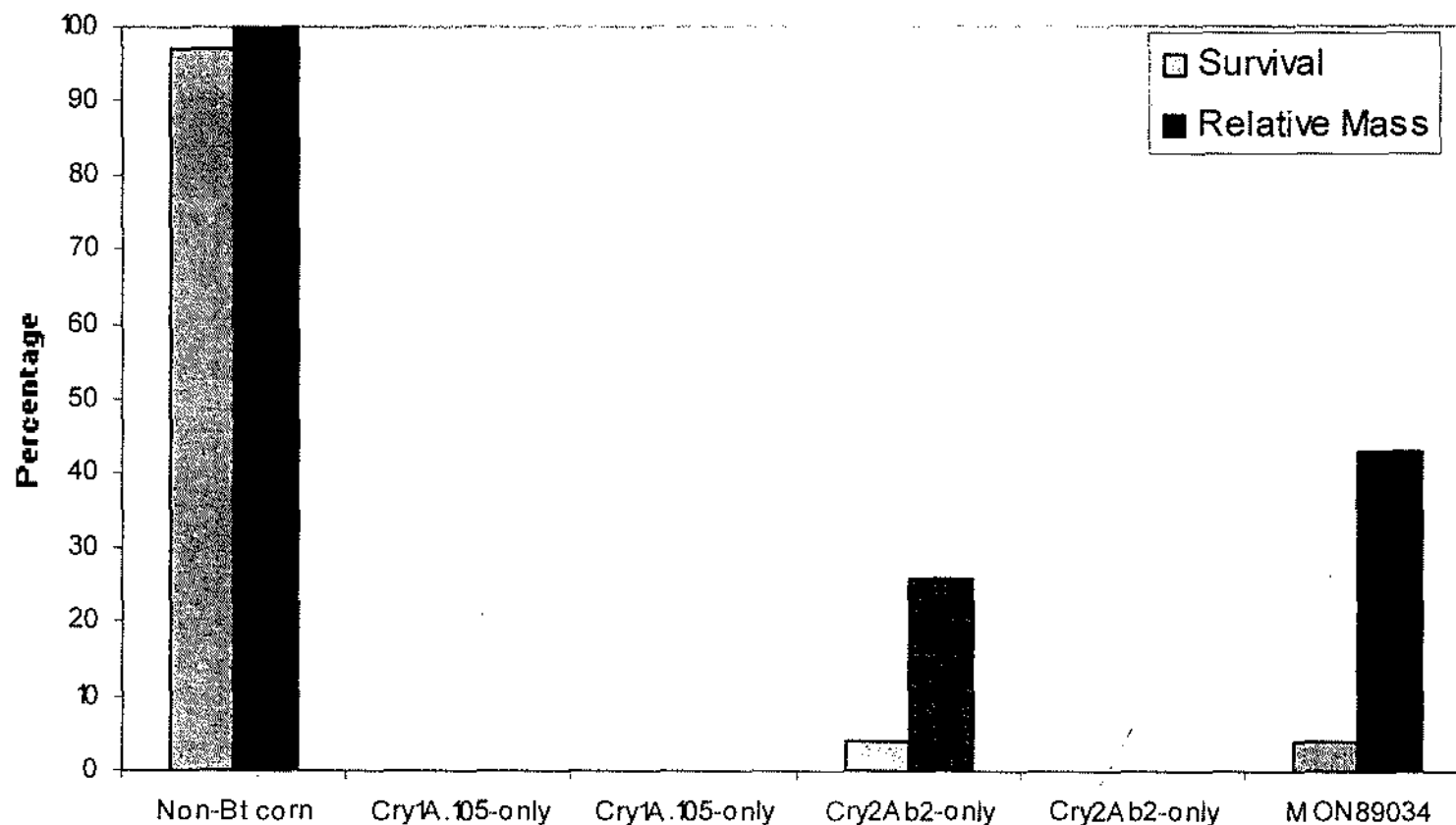
- Differences in binding characteristics of Cry1Ab and Cry1A.105
- No significant cross-resistance of Cry1Ab-resistant ECB to Cry1A.105
- No evidence of increased Cry1Ab-resistant allele frequencies in US populations of ECB, SWCB and CEW over the past decade

Level of Control MON 89034: *in vitro* protein assays

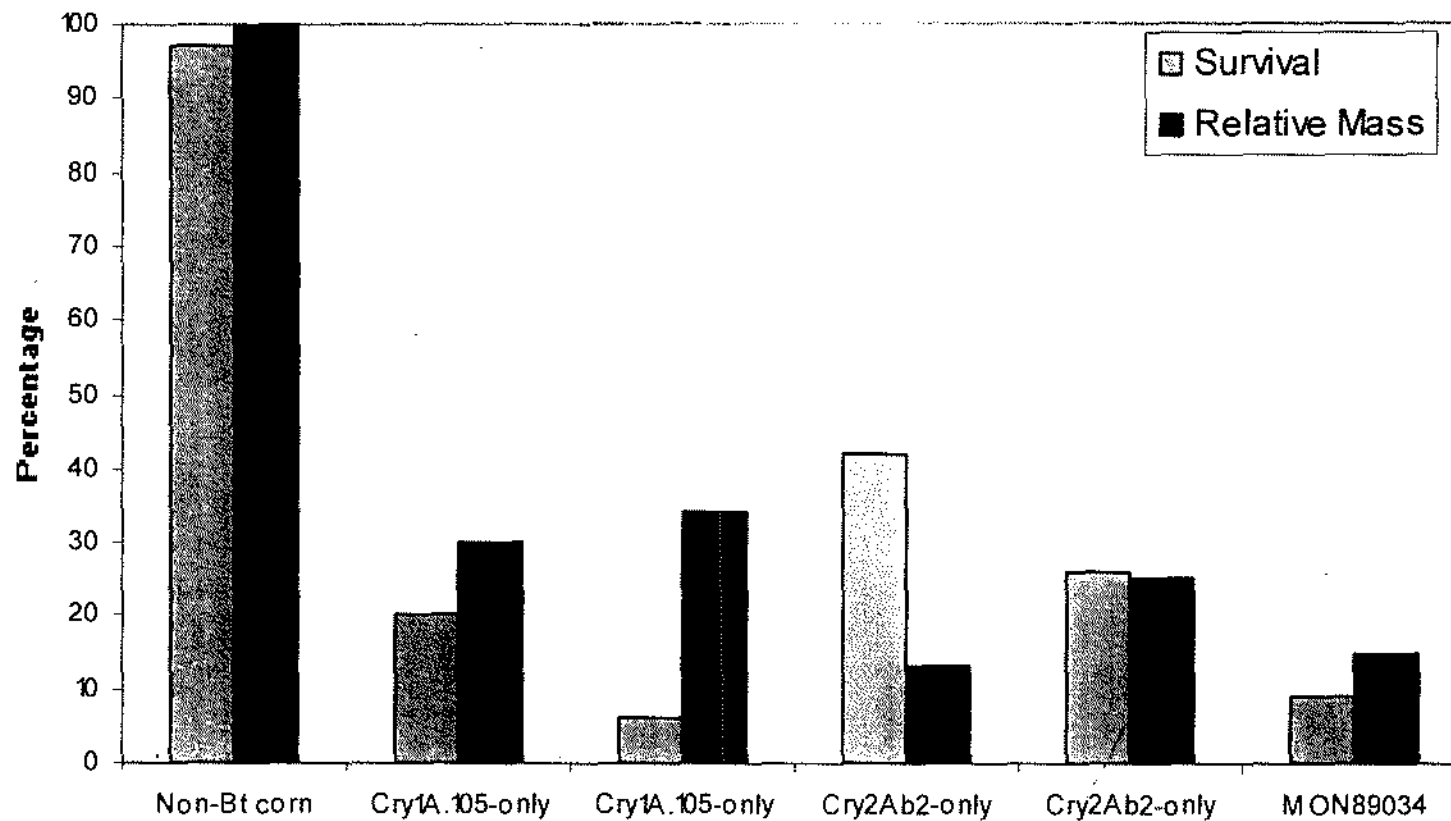
Species	MIC ₉₀ (ppm)	
	Cry1A.105	Cry2Ab2
ECB	0.36	3.40
SWCB	5.40	28.4
CEW	10.7	52.9

- Compare with MON 89034 expression levels in leaf of 20-30 ppm for Cry1A.105 and Cry2Ab2

ECB Control b MON 89034: *in planta* (leaf) assays



SWCB Control MON 89034: *in planta* (leaf) assays

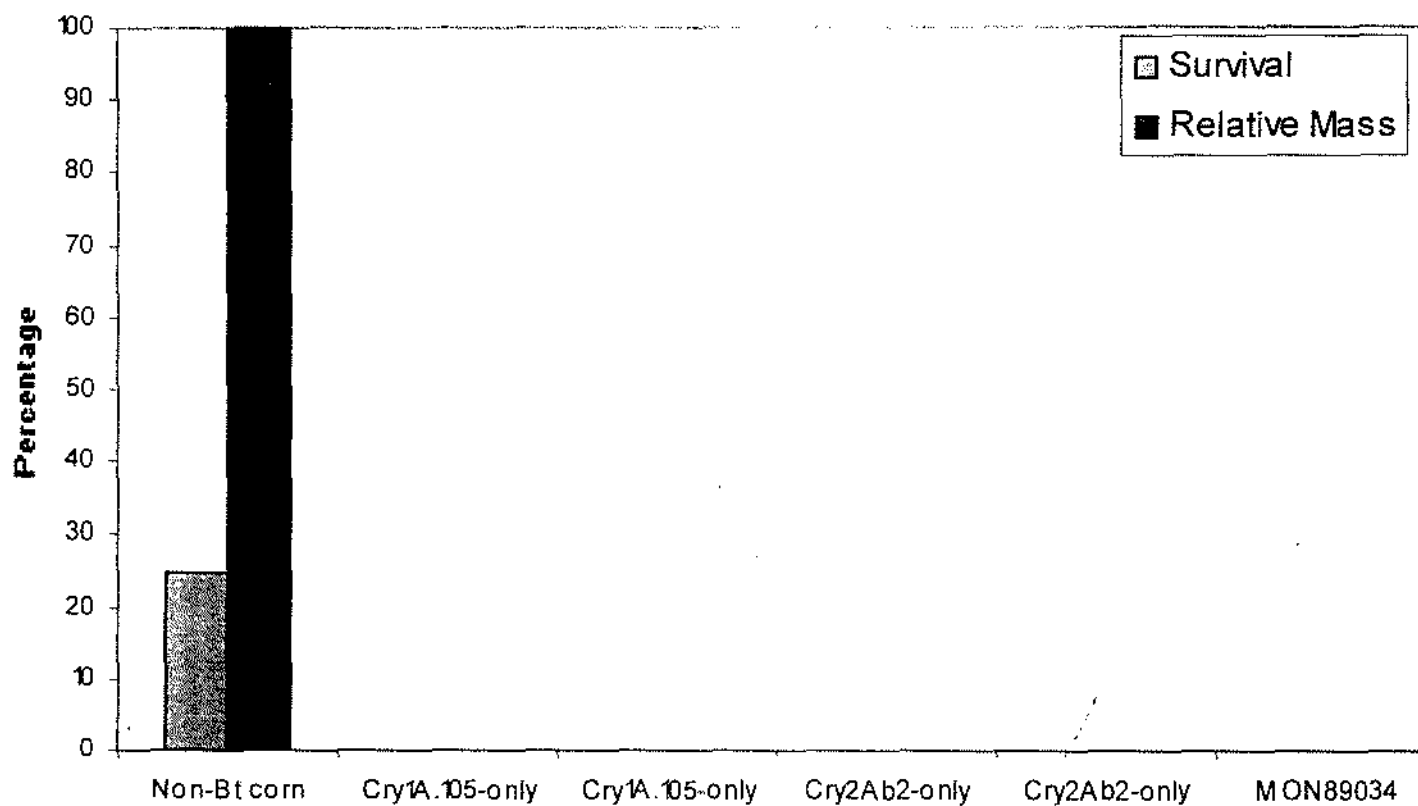


Note the small size of surviving larvae.

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CEW Control b MON 89034: *in planta* (leaves) assays



Level of Control MON 89034: Overall Control

- ECB: DED (>>95% control from each protein) level of control
- SWCB: approximately 95% control (probably greater) for Cry1A.105 and approx. 90% control for Cry2Ab2
- CEW: similar pattern to SWCB

Modeling MON 89034 Durability:

Conclusions

- Conservatively fitted by the modeling of Roush that assumed partially recessive resistance (the DBM model)
- ECB: level of control by each protein is so high that a refuge $\ll 5\%$ could still provide durability equivalent to current single-gene products
- SWCB/CEW: level of control by each protein is approximately 95% (and CEW over-wintering is very limited in this region) so a 5% refuge supportable

Modeling MON 89034 Durability: Cotton-growing Region

- ❑ Used modeling developed for Natural Refuge initiative to model CEW in the southern US
- ❑ Assumed that Natural Refuge is granted for Bollgard II cotton and MON 89034 is fully cross-resistance to Bollgard II
- ❑ 20% refuge gives 25 yr durability

IRM Plan for MON 89034

- 5% refuge size proposed for the Corn Belt based on the two independent, highly effective modes of action of Cry1A.105 and Cry2Ab2
- 20% refuge size proposed for cotton-growing areas – complements CRW
- IRM elements otherwise comparable to current products
- Risk reduced relative to single-gene products with current refuge sizes

IRM Meeting

January 25, 2007

Name

phone #

Suzanne Cervelli

308-8072

Natalia Bogdanova

314 694-3143

Graham Head

314 694-7311

Linda Lohman

314-694-3072

Patricia Moe

703 305-0744

Michael Medeiros

703 308-8715

Tessa Molsky

703 308 0455

Russ Schneider

202 383 2866

Sharlene Matten

703-605-0514

Alan Reynolds

703-605-0515



"BOGDANOVA,
NATALIA N [AG/1000]"
<natalia.n.bogdanova
@monsanto.com>

01/22/2007 04:30 PM

To Susanne Cerrelli/DC/USEPA/US@EPA

Mike Mendelsohn/DC/USEPA/US@EPA, "SCHNEIDER,
cc RUSSELL P [AG/1920]"
<russell.p.schneider@monsanto.com>

bcc

Subject RE: EPA File Symbols: 524-LTA and 524-LTL please see
attached letter

Natalia Bogdanova
Granham Head

89034

replacement

88110

combo

2.

89034x 88017

Benefits → outline

will help w/

↳ Shire gave today

benefits analysis
needed for

cond. Reg

2004-2006 - have efficacy data

• Dual efficacy data > 95% control

Dear Ms. Cerrelli,

As I am preparing a response to the Agency's letter from January 17 I would like to clarify question #3:

"The tolerance petitions request that 40 CFR Part 180 be amended to remove time limitations for the temporary exemptions from the requirement of a tolerance. These need to be modified so that you request to amend 40 CFR Part 174.453 and 174.464 to make them permanent exemptions from the requirement of a tolerance. Temporary tolerance exemptions not only have limitations, but are linked to specific experimental use permits."

The petitions from Monsanto (November 14, 2006) were to "remove time limitation by amending temporary exemption from the requirement of a tolerance for *Bacillus thuringiensis* CryIA.105 (Cry2Ab2) insecticidal protein and the genetic material necessary for its production in corn when used as plant-incorporated protectant in food and feed commodities of field corn, sweet corn and popcorn (40CFR §174.453)." 40CFR §174.454 for Cry2Ab2.

References to 40CFR §174.453 and 40CFR §174.454 are given on the titles in the parentheses. Please, let me know whether any other place in the petition would be appropriate for this reference or the current title is sufficient.

I would appreciate your clarification on the subject.

We would like to address IRM-related questions during the upcoming meeting (January 25) and will include the response in the letter that will follow.

We plan to address all indicated questions in a formal response by January 31, 2007. Please, let me know if you have any additional questions or suggestions.

Thank you very much. Look forward to meeting you on Thursday.

Best regards,
Natalia

-----Original Message-----

From: Cerrelli.Susanne@epamail.epa.gov
[mailto:Cerrelli.Susanne@epamail.epa.gov]

Sent: Wednesday, January 17, 2007 2:53 PM
To: BOGDANOVA, NATALIA N [AG/1000]
Cc: Mendelsohn.Mike@epamail.epa.gov
Subject: EPA File Symbols: 524-LTA and 524-LTL please see attached letter

Dear Dr. Bogdanova and Dr. Schneider-

Please contact me at your earliest convenience concerning any questions that you may have regarding the attached document..

(See attached file: ~7841785.pdf)

Regards,

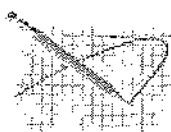
Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077 (w)

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Mike
Mendelsohn/DC/USEPA/US
A/US

01/22/2007 04:16 PM

To Rebecca Edelstein/DC/USEPA/US@EPA, Susanhe
Cerrelli/DC/USEPA/US@EPA

cc

bcc

Subject Fw: MON 89034

Rebecca,

FYI in response to your email. Also, as you are aware they did subsequently submit the tolerance exemptions.

Best Regards,

Mike

----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 01/22/2007 04:13 PM -----



"SCHNEIDER,
RUSSELL P
[AG/1920]"
<russell.p.schneider@
monsanto.com>

11/02/2006 05:58 PM

To Mike Mendelsohn/DC/USEPA/US@EPA

cc

Subject MON 89034

Mike,

Per your questions this morning, the application for the full tolerance exemption was not submitted. Since the temporary does not expire until 2009, we thought we would be OK. However, we will make the required submission.

The toxicology data for Cry2Ab2 was submitted in lieu of the recommendation from EPA in the DER to provide characterization of the plant-produced Cry2Ab2 specifically for MON 89034. For MON 89034 studies the Cry2Ab2 protein was produced in *E. coli* and for BGII - wild type protein from Bt. *In planta*, and *E. coli* -produced Cry2Ab2 differ from Bt- produced by one amino acid. Also, the original studies were done quite some time ago and questions on methods, etc. have been raised and we do not have any of the old protein left to demonstrate equivalence. Therefore a few studies were repeated using *E. coli* protein for which we have demonstrated equivalence. The following toxicology studies we submitted are repetitive for Cry2Ab2. Let me know if this is a problem.

- Digestibility in digestive tract (SGF and SIF)
- Acute mouse
- Bioinformatics - we have used updated databases and methods.

How about if we meet November 22, around 1:30?

Russ

This e-mail message may contain privileged and/or confidential information, and is intended to be received only by persons entitled to receive such information. If you have received this e-mail in error, please notify the sender immediately. Please delete it and all attachments from any servers, hard drives or any other media. Other use of this e-mail by you is strictly prohibited.

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Rebecca
Edelstein/DC/USEPA/U
S

01/22/2007 04:08 PM

To Mike Mendelsohn/DC/USEPA/US@EPA, Susanne
Cerrelli/DC/USEPA/US@EPA
cc
bcc
Subject MON 89034 submission

Mike and Susanne,

I'm reviewing data submitted by Monsanto for MON 89034, and I'm wondering why they've redone the safety studies for Cry2Ab2. For the EUP, they relied on previously submitted data: Safety data on Cry2Ab2 were reviewed previously in a memorandum from M. Watson to M. Mendelsohn dated Feb. 12, 2001 (MRIDs 44966602 Acute Oral Toxicity Study; 44966603 *In vitro* Digestibility; 44966604 Bioinformatics Analysis—Allergen Database; 44966605 Bioinformatics Analysis—Toxin and Public Domain Genetic Databases). We told Monsanto that for the registration, they needed to show equivalence between the plant produced Cry2Ab2 from event MON 89034 and the *E. coli* produced protein used in the safety studies, but I don't see why they've redone all of the safety studies, unless the *E. coli* protein used in the previously submitted studies in fact wasn't equivalent to the plant-produced protein. Do you know why they've repeated the studies?

Thanks,

Rebecca

Rebecca Edelstein, Ph.D., Chemist
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticides Programs
US Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, DC 20460
Phone: 703-605-0513
Fax: 703-305-0118

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 17 2007

Dr. Natalia N. Bogdanova
Regulatory Affairs Manager
Monsanto Company
800 N. Lindberg Blvd.
St. Louis, MO 63167

Dear Dr. Bogdanova:

Subject: **MON89034 x MON 88017 (Cry1A.105, Cry2Ab2 and Cry3Bb1) Corn and
MON89034 (Cry1A.105, and Cry2Ab2) Corn
EPA Petition Numbers: 6F7142 and 6F7143
EPA File Symbols: 524-LTA and 524-LTL**

Your applications as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for this action category (B81 twice) by June 10, 2008. Upon review of the subject applications, we have determined that they are incomplete.

The applications will be kept open for a period of 75 days from the date of this letter to give you an opportunity to address the deficiencies listed below. If you find that you need more time to satisfy the requirements, you must request an extension in advance of the 75-day compliance date, and commit to satisfy the deficiencies within a reasonable, stated, period of time. Your time extension request must also include an explanation of why additional time is required. If you do not comply with this procedure, the Agency may administratively withdraw your application from further consideration and retire this file without further notice to you, in accordance with 40 CFR 152.105. Once this is done, you will have to submit a complete new application should you wish to pursue these actions.

Based upon your response, we may need to renegotiate the current PRIA date of June 10, 2008. In the interim period, we are placing the data received thus far into scientific review.

The following deficiencies must be addressed:

- 1) The insect resistance management (IRM) package for MON 89034 X MON 88017 is deficient. There is no bridging rationale provided that links the dose and efficacy of the stacked product to that of each single gene product for each target pest as justification for the proposed IRM plan for the stacked product.
- 2) Expression data are necessary for popcorn and sweet corn in order to perform the IRM assessment.

CONCURRENCES							
SYMBOL	7511P	7511P	7511P				
SURNAME	Stenroth	Miller	Ruff				
DATE	1/11/2007	1/11/07	1/11/07				294

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

2.

- 3) The tolerance petitions request that 40 CFR Part 180 be amended to remove time limitations for the temporary exemptions from the requirement of a tolerance. These need to be modified so that you request to amend 40 CFR Part 174.453 and 174.464 to make them permanent exemptions from the requirement of a tolerance. Temporary tolerance exemptions not only have time limitations, but are linked to specific experimental use permits.
- 4) Submit revised labeling consistent with that approved for your MON 88017 product. OECD unique identifiers should appear in the ingredient name for events MON 88017 and MON 89034 and the directions for use and insect resistance management sections should be consistent. Field corn, popcorn, and sweet corn should also be addressed.
- 5) Marker proteins and inerts need to be listed on the confidential statement of formula (CSF).

On December 14, 2006, your associate, Dr. Russ Schneider indicated that he was interested in meeting with our staff to address any questions that we may have concerning these pending applications. In addition to the required information listed above, we wish to inform you of materials that would assist in expediting the review of your submission, and questions that we wish to discuss at such a meeting.

Concerning the IRM assessment we have the following questions:

- 1) What are the relative contributions of each toxin (i.e., dose of each toxin and selection)? Explain "dose" studies and your assumptions about dominance and inheritance of resistance.
- 2) How is Roush's model used for predicting resistance (relative contribution of each toxin) to ECB? What are the assumptions?
- 3) What information, relative to each toxin, is being fitted to the Monsanto revised bollworm model?

A CD with writable "MS word" files of the submitted data would facilitate incorporating tables, graphs, and other data from your submissions in our reviews.

Please contact Susanne Cerrelli of my staff at (703) 308-8077 should you have any questions or wish to schedule a meeting.

Sincerely,



Sheryl Rally, Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Rebecca
Edelstein/DC/USEPA/US

12/22/2006 09:10 AM

To Sharlene Matten/DC/USEPA/US@EPA, Susanne
Cerrelli/DC/USEPA/US@EPA
cc Mike Mendelsohn/DC/USEPA/US@EPA

bcc

Subject Re: letter to monsanto- OK?? MON89034x Mon88017 and
MON 89034

I will probably need some SOPs from Monsanto, but it'll take me awhile to figure out exactly what I need, so don't wait on me-- go ahead and send the letter. I just have one comment on the letter-- we have expression level data for the stacked product and the individual events (separate studies), so I'm not sure what we're asking for in item 1.

Rebecca
Sharlene Matten/DC/USEPA/US

Sharlene
Matten/DC/USEPA/US

12/21/2006 05:38 PM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc Mike Mendelsohn/DC/USEPA/US@EPA, Rebecca
Edelstein/DC/USEPA/US@EPA

Subject Re: letter to monsanto- OK?? MON89034x Mon88017 and
MON 89034

Susanne -- I concur with this letter. Thank you for letting me see it before it goes forward.
Sharlene

Susanne Cerrelli/DC/USEPA/US



Susanne
Cerrelli/DC/USEPA/US

12/21/2006 04:04 PM

To Mike Mendelsohn/DC/USEPA/US@EPA

cc Sharlene Matten/DC/USEPA/US@EPA, Rebecca
Edelstein/DC/USEPA/US@EPA

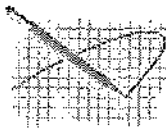
Subject letter to monsanto- OK?? MON89034x Mon88017 and MON
89034

Here's the letter again. Rebecca do you need anything else for your review? If you need much more time we can deal with your needs in a separate communication to Monsanto.

[attachment "524-LTA and LTL screen4.doc" deleted by Rebecca
Edelstein/DC/USEPA/US]

Mike- I also need to check with you about PRIA dates for this submission.

Thanks!!



Mike
Mendelsohn/DC/USEP
A/US

t t/02/2006 08:20 AM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc

bcc

Subject

Susanne,

Could you prepare the package for screening by separating it according to discipline and providing each discipline a copy of the cover letters and data matrixes? I put the file jackets in your space in the file room. FYI - I called Monsanto this AM and they are going to get back to us regarding the tolerance petitions (they may not have submitted them) and the reason why new health effects data were submitted (we already have temporary exemptions and some of the data is being resubmitted).

I will set up a meeting next week where we can go over before distribution to the team. Since Rebecca is out, we will give the health and characterization package to John. Thanks.

Mike

----- Forwarded by Mike Mendelsohn/DC/USEPA/US on t t/02/2006 08:15 AM -----



Patricia
Moe/DC/USEPA/US
t0/3 t/2006 03:59 PM

To Mike Mendelsohn/DC/USEPA/US@EPA

cc

Subject

Mon 89034 1A.105 & Cry2Ab2)
Reg Nos.: 524-LTA and 524-LTL

The team is as follows

RAL: Mike/Susanne

HH/Prod Char: Rebecca

Eco: Tessa/Mika

IRM: Sharlene

Mike: The package is ready for Preliminary screening. It is on your shelf in the fileroom DH will assign in OPPIN tomorrow. P

Patricia Moe
Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs/ U.S. EPA
phone: 703-305-0744
FAX: 703-308-7026

Date

Checklist for Data Packages/Administrative Materials

e Material (524-CTA

IAL

Susanne Corbelli + Mike Mendelsohn

Name of active ingredient

MON89034X

MON88017

Admin Materials	Signed	Date	Present	Absent	Comments
Form 8570-1	<input checked="" type="checkbox"/>	9/17/06	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
CSF - Completely filled out & original signature	<input checked="" type="checkbox"/>	9/14/06	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Method of Support	<input checked="" type="checkbox"/>	11/29/06	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Label	<input checked="" type="checkbox"/>				
Physical address of manufacturer on label	<input checked="" type="checkbox"/>				
Data Matrix - Two/one for jacket; one for FOIA	<input checked="" type="checkbox"/>				
Transmittal letters	<input checked="" type="checkbox"/>				
Petition/amended petition if food tolerance or exemption/amended food tolerance or exemption	<input checked="" type="checkbox"/>				In house - counterweights
FR template if food tolerance or exemption/amended food tolerance or exemption	<input checked="" type="checkbox"/>				N/A
Data Compensation forms, if required					
Minutes on data requirements (pre-registration meeting)					
Active ingredient # i.e. Chemical PC code					
Jacket from EPA Identifying Symbol	<input checked="" type="checkbox"/>				524-CTA
Background Experimental Use Permit Information, if applicable					

Susanne + Mike mentioned will probably need a benefits pkg if this goes "conditional"

Susanne also needs budget rationale

862

Tessa
Milofsky/DC/USEPA/U
S

11/22/2006 10:56 AM

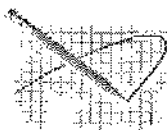
To Susanne Cerrelli/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA
cc Zigfridas Vaituzis/DC/USEPA/US@EPA, Mika
Hunter/DC/USEPA/US@EPA

bcc

Subject MON89034 x MON88017

The eco team has determined that the MON89034 and MON89034 x MON88017 packages pass the screen, provided that bridging rationale is submitted for the MON89034 x MON88017 stack.

-Tessa



Sharlene
Matten/DC/USEPA/US
t t/20/2006 03:37 PM

To Mike Mendelsohn/DC/USEPA/US@EPA, Susanne
Cerrelli/DC/USEPA/US@EPA
Alan Reynolds/DC/USEPA/US@EPA, Tessa
cc Milofsky/DC/USEPA/US@EPA, Mika
Hunter/DC/USEPA/US@EPA, Patricia
bcc
Subject IRM and Benefits screening for MON 89034 and MON 89034
X MON 880 t7

Mike and Susanne --

The IRM package for MON 89034 passes the initial screen. However, no one mentioned that the registration application includes sweet corn and popcorn. The IRM plan for sweet corn is for a non-structured refuge because of the cultural practices and growing season (shorter) -- overwintering destruction methods. The IRM plan for popcorn is identical to that of field corn. I think I may have some questions about the modeling that was done, but that will come later.

The IRM package for MON 89034 X MON 88017 is deficient. There is no bridging rationale provided. At a minimum, Monsanto must provide information about the dose of the stacked product vs. each single gene product and the expression of the stacked product vs. each single gene product.

There is no benefits package for either new active ingredient, Cry1A.105 or Cry2Ab2, in corn. Every Bt corn PIP, with the exception of the NK Bt 11, was conditionally registered registered under 3(c)7(C) and therefore required the Agency to make a public interest finding based on a benefits assessment. Therefore, Monsanto should provide a public interest document. I expect there will be conditions of registration and these registrations will be time-limited.

Sharlene

11-16-06

City 2AB2 → Bollgard 2
→ Ecodata for EUP
EUP → ^{was} _n for Both

Screen Notes Mon 89034 x Mon 88017

8034-3 for Stack

July 2006 ^{needed} for EUP

asked for ~~info~~ Spengerson Study for Lab

Insect Bioassay of combined trail

MRED#

— doesn't meet

req outlined

Mika's

DER for

July 6, 2006

dosing ^{justified} question for Eco studies for Fuxel

Ensure waivers for 158 requirements
esp → pubh staff

Shallone → needs to know
expression level w/ proteins

324-LFA
IKM Stack - limited

Benefits package missing

in future may require

→ Non target

→ Soil degradation

Nov 28th meeting →
to discuss when benefits review
req'd

P7 funding

3b

1a05

MONSANTO



469513-00

Notalio N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314)-694-3382

MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005-7211
PHONE (202) 783-2460
FAX (202) 789-1819
<http://www.monsanto.com>

September 29, 2006

Document Processing Desk (EUP)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subj: Application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins produced in MON 89034 x MON 88017

Dear Dr. Reilly:

Please find enclosed an application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins and the genetic material necessary for their production in the corn product MON 89034 x MON 88017. This application is being submitted concurrently with a separate application for the registration of the Bt Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in MON 89034 corn.

MON 89034 x MON 88017 was developed by conventional breeding of plants containing MON 89034 with plants containing MON 88017. MON 89034 is a second-generation product that produces Cry1A.105 and Cry2Ab2 proteins, which together control a wider spectrum of lepidopteran pests and offers an enhanced insect resistance management (IRM) tool compared to the current lepidopteran-protected corn product MON 810. MON 88017 produces a variant of the wild-type Cry3Bb1 protein from Bt subsp. *kumamotoensis* that protects the roots of corn plants from feeding damage caused by the coleopteran pest, corn rootworm (*Diabrotica* sp.). MON 88017 also expresses the 5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), which confers tolerance to glyphosate, the active ingredient in the Roundup® family of agricultural herbicides. In 2005 the EPA granted a registration for the Cry3Bb1 protein and the genetic material necessary for its production in MON 88017 (EPA Reg. No. 524-551).

® Roundup is a registered trademark of Monsanto Technology LLC.

EPA established temporary exemptions from the requirement of a tolerance for the Cry1A.105, Cry2Ab2 proteins and the genetic material for their production in corn (40 CFR §174.453 and 40 CFR §174.454, respectively). The Cry3Bb1 protein and the genetic material necessary for its production in corn are also exempt from the requirement of a tolerance (40 CFR §180.1214). The CP4 EPSPS protein has been classified as a plant pesticide inert ingredient and is exempt from the requirement of a tolerance in all crops (40 CFR §180.1174).

This application includes the following documents that, for purposes of placement in the Public Docket, have been classified as 'A' (non-confidential documents that can be released to the public), 'B' (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers), or 'C' (confidential business information). In addition, pdf files are included on a CD-ROM for placing documents classified as 'A' on the Edocket. The redacted version of the Administrative volume (.pdf file) for the Edocket excludes the data matrix (agency internal use copy) and confidential attachment. Complete description of this submission by category is provided in the attachment to this letter.

It is Monsanto's understanding that the following fee category and amount is appropriate based on the June 2, 2005 Federal Register notice for Pesticide fees and Decision Times:

- Fee category B33: New product developed by stacking PIP traits within a crop using traditional breeding techniques
- Fee Category Amount: \$26,250

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

A handwritten signature in black ink, appearing to read "N. Bogdanova", followed by the text "(for)" in parentheses.

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto
Monsanto Regulatory Files

ATTACHMENT

Volume	Category	Document	Hard Copy	.pdf file for EdoCKET
N/A	A	Cover letter	√	√
N/A	A	Transmittal document	√	√
1	A	Administrative volume	√	
1	C	Confidential statement of formula	√	
1	A	Administrative volume (redacted copy)		√
2	B	Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins Produced in Insect-protected Corn MON 89034 x MON 88017.	√	
3	B	Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis.	√	
4	B	Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-Protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials.	√	
5	B	An Evaluation of the Insect Bioefficacy of Combined Trait Products Produced Through Conventional Breeding: MON 89034 x NK603 and MON 89034 x MON 88017.	√	
6	B	Evaluation of Potential for Interactions Between the <i>Bacillus thuringiensis</i> Proteins Cry1A.105, Cry2Ab2, and Cry3Bb1.	√	
7	B	Insect Resistance Management Plan for the Combined Trait Product MON 89034 x MON 88017.	√	

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

**REGULATORY ACTION IN SUPPORT OF WHICH
THIS DOCUMENT IS SUBMITTED**

Administrative Materials for the Application to Register the Plant-Incorporated Protectant,
Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material
(Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x
MON 88017

EPA File 524 - XXX

TRANSMITTAL DATE

September 29, 2006

MONSANTO REFERENCE NO.

06-CR-177E-1

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

- Volume 1.** Bogdanova, N.N. 2006. Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017.

MRID Number Admin

Product Summary

- Volume 2.** Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins Produced in Insect-protected Corn MON 89034 x MON 88017. Monsanto Technical Report MSL-20434.

MRID Number 46951301

Product Characterization

- Volume 3.** Groat, J.R., B.J. Wolff, J.F. Rice, and J.D. Masucci. 2006. Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis. Monsanto Technical Report MSL-20145.

MRID Number 46951302

- Volume 4.** Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-Protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL0020479.

MRID Number 46951303

test
Volume 5. Levine, S.L. An Evaluation of the Insect Bioefficacy of Combined Trait Products Produced Through Conventional Breeding: MON 89034 x NK603 and MON 89034 x MON 88017. Monsanto Technical Report MSL-20336.

MRID Number 46951304

2478
Volume 6. MacRae, T.C., C.R. Brown, and S.L. Levine. Evaluation of Potential for Interactions Between the Bacillus thuringiensis Proteins Cry1A.105, Cry2Ab2, and Cry3Bb1. Monsanto Technical Report MSL-20270.

MRID Number 46951305

Volume 7. Head, G.P. Insect Resistance Management Plan for the Combined Trait Product MON 89034 x MON 88017. Monsanto Technical Report 06-RA-39-06.

MRID Number 46951306

Company Official: Natalia N. Bogdanova 09/29/06
Natalia N. Bogdanova, D.V.M. Date
Regulatory Affairs Manager
(314) 694-3143

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Director, Regulatory Affairs
(202) 383-2866

NEW APPLICATIONS

DATE: 10/3/06

FILE NUMBER: 524-LTA

FEP (OPPIN ENTRY): 10/3/06pm
(Initial & date)

FILE ROOM: LTA 10/11/06
(Initial & date)

SIG: LC 10/12/2006
(Initial & date)

FILE ROOM: JW 10-13-06
(Initial & date)

X ASSIGN TO PM 92

FEE FOR SERVICE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 10, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-371190
EPA File Symbol or Registration Number: 524-LTA
Product Name: MON 89034 X 88017
EPA Receipt Date: 29-Sep-2006
EPA Company Number: 524
Company Name: MONSANTO COMPANY

RUSSELL P. SCHNEIDER
MONSANTO CO
MONSANTO COMPANY
1300 I STREET, NW, SUITE 450 EAST
WASHINGTON, DC 20005

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

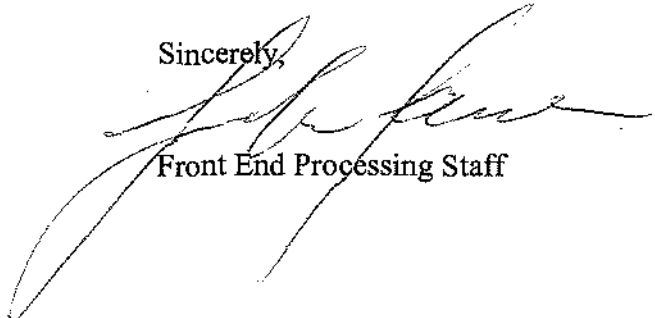
The Action has been identified as Action Code: B81.0

PIP;REGISTER NEW AI;TEMP. TOLERANCE/EXEMPTION EXISTS SAP REQUIRED;NO
FEE: LINKED TO A PRIA APPLICATION;

Please note that no fee is due for this action.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-8260.

Sincerely,


Front End Processing Staff



ADMINISTRATIVE NO(S).:

524 - LTA

MON 89034 ~ 88017

PM: 92

CHEMICAL NO.:

The jacket for this action can be
requested through the JACKETS system.

FEE FOR SERVICE

{799763T~

for Division

- New Registration
- Amendment

- ☐ AD
- ☒ BPPD
- ☐ RD

☒ Studies? ☐ Fee Waiver?

volpay % Reduction: _____

Risk Mgr.	92
-----------	----

Receipt No.

S- 799763

EPA File Symbol/Reg. No.

524-LTA

Pin-Punch Date:

9/29/2006

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B 33 (7)

Granted: 1381.0

Amount Due: \$ 100.00

Parent/Child Decisions:

Reviewer: P. Moel

Date: 5 Oct '06

Remarks: This is a ~~child~~^{PM}-child of 524-LTL. It gets a B81 timeframe but ~~no~~^{no} fee, ~~no~~^{no} ~~consequence~~^{no} ~~on~~^{no} ~~the~~^{no} ~~PM~~^{PM} (sorry for the mess.) (314)

314



VOLUME 1

Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

EPA File 524 - XXX

AUTHOR

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

SUBMISSION DATE

September 29, 2006

SUBMITTING REGISTRANT

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

MONSANTO REFERENCE NO.

06-CR-177E-1

The text below applies only to use of the data by the United States Environmental Protection Agency (U.S. EPA) in connection with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

STATEMENT OF DATA CONFIDENTIALITY CLAIM

No claim of data confidentiality is being made for information contained in this document on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). However, a supplemental data confidentiality claim is being made for some information claimed herein. The applicable information has been removed to a confidential attachment.

"We submit this material to the United States Environmental Protection Agency specifically under requirements set forth in FIFRA as amended, and consent to use and disclosure of this material by the EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to the EPA."

COMPANY: Monsanto Company

COMPANY AGENT:

Natalia N. Bogdanova
Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

DATE: September 29, 2006

GLP COMPLIANCE STATEMENT

The materials in this volume do not meet the requirements of the Good Laboratory Practice Standards, 40 CFR Part 160. This volume provides the administrative materials for the application to register the plant-incorporated protectant, *Bacillus thuringiensis thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017, and therefore were not developed in compliance with 40 CFR Part 160.

Natalia N. Bogdanova 09/29/06
Submitter Date
Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

Natalia N. Bogdanova 09/29/06
Sponsor Date
Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

Natalia N. Bogdanova 09/29/06
Study Director Date
Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

VOLUME 1
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ABBREVIATIONS AND DEFINITIONS

Bt	<i>Bacillus thuringiensis</i>
CBI	Confidential business information
CFR	U.S. Code of Federal Regulations
CSF	Confidential Statement of Formula
Cry1A.105	A chimeric protein comprised of sequences from the naturally occurring Cry1Ab, Cry1F, and Cry1Ac proteins from <i>Bacillus thuringiensis</i>
Cry2Ab2	A crystal protein derived from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IRM	Insect resistance management
MON 89034	A Monsanto corn product, and the subject of this application for registration, that produces the insecticidal <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 proteins
MRID	EPA master record identification number
NTO	Nontarget organism
PR Notice	EPA Pesticide Registration notice
PV-ZMIR39	Deoxyribonucleic acid vector (genetic material) used in the transformation of corn to produce MON 88017
PV-ZMIR245	Deoxyribonucleic acid vector (genetic material) used in the transformation of corn to produce MON 89034

SECTION I

ADMINISTRATIVE MATERIALS

Application for Registration (Form 8570-1)

Confidential Statement of Formula (Form 8570-4)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY****401 M Street, S. W.
WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 (314) 694-3143	EPA Registration Number / File Symbol: 524-XXX
Active Ingredient(s) and/or representative test compound(s): Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017	Date: September 29, 2006
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 x MON 88017

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date September 29, 2006	Typed or Printed Name and Title Natalia N. Bogdanova Regulatory Affairs Manager
---------------	----------------------------	---

EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.



United States
Environmental Protection Agency
 Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier
 Number

Application for Pesticide – Section I

1. Company/Product Number File Symbol 524- MMX LTA	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) MON 89034 x MON 88017	PM # 28 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application to Register the Plant-Incorporated Protectant *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Section – III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container
Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Russell P. Schneider		Title Director, Regulatory Affairs		Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Natalia N. Bogdanova</i>		3. Title Regulatory Affairs Manager			
4. Typed Name Natalia N. Bogdanova Tel. (314) 694-3143		5. Date September 29, 2006			

MONSANTO



Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager
(314)-694-3382

MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005-7211
PHONE (202) 783-2460
FAX (202) 789-1819
<http://www.monsanto.com>

September 29, 2006

Document Processing Desk (EUP)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subj: Application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins produced in MON 89034 x MON 88017

Dear Dr. Reilly:

Please find enclosed an application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins and the genetic material necessary for their production in the corn product MON 89034 x MON 88017. This application is being submitted concurrently with a separate application for the registration of the Bt Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in MON 89034 corn.

MON 89034 x MON 88017 was developed by conventional breeding of plants containing MON 89034 with plants containing MON 88017. MON 89034 is a second-generation product that produces Cry1A.105 and Cry2Ab2 proteins, which together control a wider spectrum of lepidopteran pests and offers an enhanced insect resistance management (IRM) tool compared to the current lepidopteran-protected corn product MON 810. MON 88017 produces a variant of the wild-type Cry3Bb1 protein from Bt subsp. *kumamotoensis* that protects the roots of corn plants from feeding damage caused by the coleopteran pest, corn rootworm (*Diabrotica* sp.). MON 88017 also expresses the 5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), which confers tolerance to glyphosate, the active ingredient in the Roundup® family of agricultural herbicides. In 2005 the EPA granted a registration for the Cry3Bb1 protein and the genetic material necessary for its production in MON 88017 (EPA Reg. No. 524-551).

® Roundup is a registered trademark of Monsanto Technology LLC.

EPA established temporary exemptions from the requirement of a tolerance for the CryIA.105, Cry2Ab2 proteins and the genetic material for their production in corn (40 CFR §174.453 and 40 CFR §174.454, respectively). The Cry3Bb1 protein and the genetic material necessary for its production in corn are also exempt from the requirement of a tolerance (40 CFR §180.1214). The CP4 EPSPS protein has been classified as a plant pesticide inert ingredient and is exempt from the requirement of a tolerance in all crops (40 CFR §180.1174).

This application includes the following documents that, for purposes of placement in the Public Docket, have been classified as 'A' (non-confidential documents that can be released to the public), 'B' (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers), or 'C' (confidential business information). In addition, pdf files are included on a CD-ROM for placing documents classified as 'A' on the Edocket. The redacted version of the Administrative volume (.pdf file) for the Edocket excludes the data matrix (agency internal use copy) and confidential attachment. Complete description of this submission by category is provided in the attachment to this letter.

It is Monsanto's understanding that the following fee category and amount is appropriate based on the June 2, 2005 Federal Register notice for Pesticide fees and Decision Times:

- Fee category B33: New product developed by stacking PIP traits within a crop using traditional breeding techniques
- Fee Category Amount: \$26,250

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

A handwritten signature in black ink, appearing to read "N. Bogdanova", followed by the text "(for)" in parentheses.

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto
Monsanto Regulatory Files

ATTACHMENT

Volume	Category	Document	Hard Copy	.pdf file for EdoCKET
N/A	A	Cover letter	√	√
N/A	A	Transmittal document	√	√
1	A	Administrative volume	√	
1	C	Confidential statement of formula	√	
1	A	Administrative volume (redacted copy)		√
2	B	Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins Produced in Insect-protected Corn MON 89034 x MON 88017.	√	
3	B	Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis.	√	
4	B	Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-Protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials.	√	
5	B <i>Eco</i>	An Evaluation of the Insect Bioefficacy of Combined Trait Products Produced Through Conventional Breeding: MON 89034 x NK603 and MON 89034 x MON 88017.	√	
6	B	Evaluation of Potential for Interactions Between the <i>Bacillus thuringiensis</i> Proteins Cry1A.105, Cry2Ab2, and Cry3Bb1.	√	
7	B <i>IRM</i>	Insect Resistance Management Plan for the Combined Trait Product MON 89034 x MON 88017.	√	

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Register the Plant-Incorporated Protectant,
Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material
(Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x
MON 88017

EPA File 524 - XXX

TRANSMITTAL DATE

September 29, 2006

MONSANTO REFERENCE NO.

06-CR-177E-1

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

- Volume 1.** Bogdanova, N.N. 2006. Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017.

MRID Number _____

Product Summary

- Volume 2.** Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins Produced in Insect-protected Corn MON 89034 x MON 88017. Monsanto Technical Report MSL-20434.

MRID Number _____

Product Characterization

- Volume 3.** Groat, J.R., B.J. Wolff, J.F. Rice, and J.D. Masucci. 2006. Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis. Monsanto Technical Report MSL-20145.

MRID Number _____

- Volume 4.** Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-Protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL0020479.

MRID Number _____

Volume 5. Levine, S.L. An Evaluation of the Insect Bioefficacy of Combined Trait Products Produced Through Conventional Breeding: MON 89034 x NK603 and MON 89034 x MON 88017. Monsanto Technical Report MSL-20336.

MRID Number _____

Volume 6. MacRae, T.C., C.R. Brown, and S.L. Levine. Evaluation of Potential for Interactions Between the Bacillus thuringiensis Proteins CryIA.105, Cry2Ab2, and Cry3Bb1. Monsanto Technical Report MSL-20270.

MRID Number _____

Volume 7. Head, G.P. Insect Resistance Management Plan for the Combined Trait Product MON 89034 x MON 88017. Monsanto Technical Report 06-RA-39-06.

MRID Number _____

Company Official: Natalia N. Bogdanova 09/29/06
Natalia N. Bogdanova, D.V.M. Date
Regulatory Affairs Manager
(314) 694-3143

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Director, Regulatory Affairs
(202) 383-2866

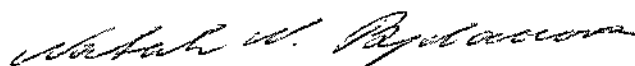


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DATA MATRIX

Date: September 29, 2006		EPA Reg. No./File Symbol: 524-XXX		Page 1 of 25	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRIQ Number	Submitter	Status	Note
885.2500	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-Protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL0020479.		Monsanto Company	OWN	This Submission
885.2100	MacRae, T.C., C.R. Brown, and S.L. Levine. Evaluation of Potential for Interactions Between the Bacillus thuringiensis Proteins Cry1A.105, Cry2Ab2, and Cry3Bb1. Monsanto Technical Report MSL-20270.		Monsanto Company	OWN	This Submission
	Head, G.P. Insect Resistance Management Plan for the Combined Trait Product MON 89034 x MON 88017. Monsanto Technical Report 06-RA-39-06.		Monsanto Company	OWN	This Submission
	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins Produced in Insect-protected Corn MON 89034 x MON 88017. Monsanto Technical Report MSL-20434.		Monsanto Company	OWN	This Submission
885.2100	Groat, J.R., B.J. Wolff, J.F. Rice, and J.D. Mastacci. 2006. Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis. Monsanto Technical Report MSL-20145.		Monsanto Company	OWN	This Submission
Signature 			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager		Date September 29, 2006

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Monsanto Company

06-CR-177E-1

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DATA MATRIX

Date: September 29, 2006		EPA Reg. No./File Symbol: 524-XXX		Page 2 of 25	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis CryIA.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.		Monsanto Company	OWN	
885.1100 885.1200 885.1300 885.2100	Rice, J.F., B.J. Wolff, J.R. Groar, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.		Monsanto Company	OWN	
885.1400 885.1500 885.2200 885.2400 885.2500	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the CryIA.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.		Monsanto Company	OWN	
885.2100	Kartananandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E. coli-Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.		Monsanto Company	OWN	
Signature <i>Natalia N. Bogdanova</i>		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date September 29, 2006	

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DATA MATRIX

Date: September 29, 2006

EPA Reg. No./File Symbol: 524-XXX


Page 3 of 25

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.2100 885.2200	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in <i>E. Coli</i> and <i>Bt</i> Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.		Monsanto Company	OWN	
885.3050 885.4150	Bourette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto study CRO-2005-049.		Monsanto Company	OWN	
885.3050	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the <i>in vitro</i> Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.		Monsanto Company	OWN	
885.1300 885.2100 885.2200	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cry1A.105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.		Monsanto Company	OWN	
885.1300 885.2100 885.2200	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.		Monsanto Company	OWN	
Signature 			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 29, 2006	

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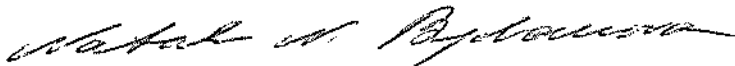
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto study number 05-01-50-13, Amended report.		Monsanto Company	OWN	
885.4340	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> CryIA.105 Protein. Monsanto Technical Report MSL-20230.		Monsanto Company	OWN	
885.4340	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> Cry2Ab2 Protein. Monsanto Technical Report MSL-20229.		Monsanto Company	OWN	
	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.		Monsanto Company	OWN	
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (<i>Folsomia candida</i>). Monsanto Technical Report MSL-20169.		Monsanto Company	OWN	
Signature			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 29, 2006	

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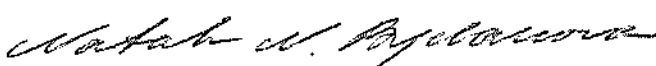
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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Pahner, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran <i>Daphnia magna</i> : An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.		Monsanto Company	OWN	
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.		Monsanto Company	OWN	
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (<i>Apis mellifera</i> L.). Monsanto study CA-2005-071.		Monsanto Company	OWN	
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (<i>Apis mellifera</i> L.). Monsanto study CA-2005-072.		Monsanto Company	OWN	
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.		Monsanto Company	OWN	
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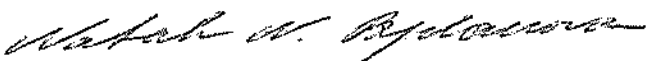
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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.		Monsanto Company	OWN	
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of CryIA.105 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthrenidae). Monsanto Technical Report MSL-20170.		Monsanto Company	OWN	
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthrenidae). Monsanto Technical Report MSL-20171.		Monsanto Company	OWN	
885.4340	Sindermann, A.B., J.R. Poreh, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to CryIA.105 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.		Monsanto Company	OWN	
885.4340	Sindermann, A.B., J.R. Poreh, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.		Monsanto Company	OWN	
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.		Monsanto Company	OWN	
885.5200	Mitch, M., T. Chnao, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.		Monsanto Company	OWN	
885.4340	Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.		Monsanto Company	OWN	
	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.		Monsanto Company	OWN	

Signature

Name and Title

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

Date

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Product: MON 89034 x MON 88017
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V.L. 2000. Evaluation of the Effect(s) of Purified Bacillus thuringiensis Cry2Ab2 Protein on Honey Bee Larvae. Monsanto Technical Report MSL-16961.	45337102	Monsanto Company	OWN	
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (<i>Apis mellifera</i> L.). Study CA-99-058, Monsanto Technical Report, MSL-16176.	45086308	Monsanto Company	OWN	
	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	46694503	Monsanto Company	OWN	
885.2100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the CryIA.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and <i>E.coli</i> -Produced CryIA.105 Proteins. Monsanto Technical Report, MSL-19960.	46694604	Monsanto Company	OWN	
Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 29, 2006	

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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3050 885.4150	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with CryIA.105 Protein. Monsanto Study CRO-2005-050.	46694603	Monsanto Company	OWN	
885.3050	Kapadia, S. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the CryIA.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	46694606	Monsanto Company	OWN	
885.3050	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and CryIA.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report, MSL-19899.	46694607	Monsanto Company	OWN	
885.4340	MaeRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the <i>Bacillus Thuringiensis</i> Proteins CryIA.105 and Cry2Ab2. Monsanto Technical Report, MSL-19859.	46694602	Monsanto Company	OWN	
885.4340	Palmer, S.J. and H.O. Kreuger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report, MSL-16177.	45086313	Monsanto Company	OWN	

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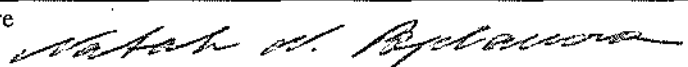
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MDN 89034 x MON 88017		
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MDN 863. Monsanto Technical Report, MSL-17137.	454240-10	Monsanto Company	OWN	
	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Produced in MON 88017. Monsanto Technical Report, MSL-18835.	461817-01	Monsanto Company	OWN	
151-20, 151-21, 151-22, 151-26 885.1100 885.1200 885.1300 885.2100	Beasley, K. A., H.M. Anderson, P.B. Wimberley, D.W. Mittank, and R.P. Lirette. 2002. Molecular analysis of YieldGard [®] Rootworm/Roundup Ready [®] corn event MON 88017. Monsanto Technical Report, MSL-17609.	461817-02	Monsanto Company	DWN	
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500 885.2200 885.2400 885.2500	Bhaktia, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS protein levels in corn tissues collected from MON 88017 corn produced in U.S. field trials conducted in 2002. Monsanto Technical Report, MSL-18823.	461817-03	Monsanto Company	OWN	
151-26 885.2100	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of functional equivalence of two Cry3Bb1 protein variants against susceptible Coleopteran species. Monsanto Technical Report, MSL-18799.	461817-04	Monsanto Company	OWN	
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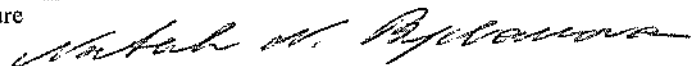
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by <i>E. coli</i> Fermentation and MON 863. Monsanto Technical Report, MSL-17274.	455382-01	Monsanto Company	OWN	
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Monsanto Company	OWN	
151-26 885.2100	Thoma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154.	454240-11	Monsanto Company	OWN	
153-4 885.2500	Dudin, Y. A., B-P. Tonnu, L. D. Albee and R. P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. Monsanto Technical Report, MSL-17181.	454240-01	Monsanto Company	OWN	
152-30 885.3050	Astwood, J. D., R. E. Hileman, M. J. McKee, T. J. Rydel, J. W. Scale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. Monsanto Technical Report, MSL-17225.	454240-09	Monsanto Company	OWN	
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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30 885.3050 885.4150	Boumette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. Monsanto Technical Report, MSL-17382.	455382-02	Monsanto Company	OWN	
152-30 885.3050	Leach, J. N., R. E. Hileman and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from <i>E. coli</i> . Monsanto Technical Report, MSL-17292.	455382-03	Monsanto Company	OWN	
152-30 885.3050	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. Monsanto Technical Report, MSL-17530.	455770-02	Monsanto Company	OWN	
151-36 885.2200	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Altergen, Toxin and Public Domain Protein Databases. Monsanto Technical Report, MSL-17140.	454240-08	Monsanto Company	OWN	
154-16 885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999). <i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. Monsanto Technical Report, MSL-16161.	449043-15	Monsanto Company	OWN	
Signature <i>Natasha N. Bogdanova</i>			Name and Title Natafia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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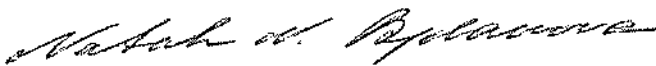


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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). Monsanto Technical Report, MSL-16166.	449043-14	Monsanto Company	OWN	
154-23 885.4340	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. Monsanto Technical Report, MSL-16162.	449043-16	Monsanto Company	OWN	
154-19 885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. Monsanto Technical Report, MSL-16164.	449043-19	Monsanto Company	OWN	
154.19 885.2600	McKee, M. J. (2001). Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. Monsanto Technical Report, MSL-17383.	455382-00	Monsanto Company	OWN	
154-20 885.4240	Drottler, K. R. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). Monsanto Technical Report, MSL-16163.	449043-18	Monsanto Company	OWN	
Signature 			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager		Date September 29, 2006

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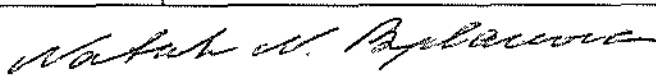
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein t1098 to Collembola (<i>Folsomia candida</i>). Monsanto Technical Report, MSL-15988.	449043-17	Monsanto Company	OWN	
154-23 885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein t1231: A Dietary Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). Monsanto Technical Report, MSL-16165.	449043-12	Monsanto Company	OWN	
154-23 885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein t1231: A Dietary Study with the Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). Monsanto Technical Report, MSL-16167.	449043-13	Monsanto Company	OWN	
154-23 885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Report. Monsanto Ref. No. 99-894E.	453484-02	Monsanto Company	OWN	
154-23 885.4340	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . Monsanto Technical Report, MSL-16936.	453613-01	Monsanto Company	OWN	
Signature 			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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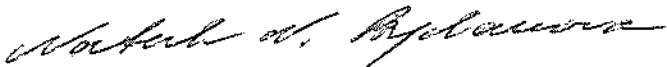


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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Bryan, R. L., J. R. Porch and H. O. Knteger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, <i>Hippodamia earmergens</i> . MSL-17171.	453613-02	Monsanto Company	OWN	
154-23 885.4340	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179.	455382-06	Monsanto Company	OWN	
154-23 885.4340	Duan, J. J., M. J. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16907.	455382-04	Monsanto Company	OWN	
154-23 885.4340	Sears, M. and M. Maitla (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (<i>Danux plexippus</i>) via Laboratory Bioassay. MSL-17235.	455382-05	Monsanto Company	OWN	
154-23 885.4340	Head, C., M. Picau, S. Sivasubramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein <i>in vitro</i> . C3NTO.	455382-07	Monsanto Company	OWN	
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. Monsanto Technical Report MSL-17614.	455770-03	Monsanto Company	OWN	
154-23 885.4340	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7.	456530-03	Monsanto Company	OWN	
154-23 885.4340	Bhatti, M. A., J. D. Duan, C. L. Pilcher, M. I. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Repon. Monsanto Technical Report MSL-17531.	457916-01	Monsanto Company	OWN	
154-23 885.4340	Sindermann, A. B., J. R. Porsch and H. O. Krieger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-18137.	457571-01	Monsanto Company	OWN	
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	
Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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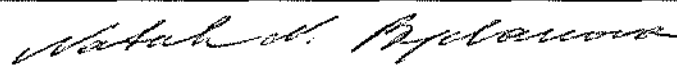
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-24 885.4380	Maggi, V. L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees (<i>Apis mellifera</i> L.). Monsanto Technical Report MSL-16169.	449043-11	Monsanto Company	OWN	
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Aerobic Soil Degradation of the <i>B.t.</i> Protein 11098 as a Component of Insect Protected Corn. Monsanto Technical Report MSL-16440.	451568-04	Monsanto Company	OWN	
885.5200	Dubelman, S., B. Ayden, M. Muehl, J. A. Warren, C. Jiang, J. Binkout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected MON 863. Monsanto Technical Report MSL-17102.	457571-02	Monsanto Company	OWN	
	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E.	450297-01	Monsanto Company	OWN	
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. Monsanto Technical Report MSL-16168.	449043-10	Monsanto Company	OWN	
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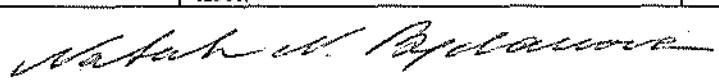
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151.26	Padgett, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-Enolpyruvylshikimate-3-phosphate Synthase from <i>Agrobacterium</i> sp. Strain CP4. Monsanto Technical Report MSL-12738.	438076-01	Monsanto Company	OWN	
151.20	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant <i>Escherichia coli</i> Fermentation. Monsanto Technical Report MSL-12389.	438076-02	Monsanto Company	OWN	
151.26	Heeren, R., S. Padgett and M. Gustafson (1993). The Purification of Recombinant <i>Escherichia coli</i> CP4 5-enolpyruvyl-shikimate-3-phosphate synthase for Equivalence Studies. Monsanto Technical Report MSL-12574.	438076-03	Monsanto Company	OWN	
885.3050	Thorp, J.J. and M.E. Goley. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938.		Monsanto Company	OWN	
151.26	Harrison, L., M. Bailey, R. Leininger, C. Smith, D. Nitta, M. Taylor, M. Gustafson, B. Heeren and S. Padgett (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30/14: 12901.	436433-01	Monsanto Company	OWN	
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Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151.26	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in <i>Escherichia coli</i> and European Corn Borer Resistant Corn. Lab Project Number: 94-01-39-10: Monsanto Technical Report MSL-13920.	436433-02	Monsanto Company	OWN	
152.30	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice: Lab Project Number: 92223.	436433-03	Monsanto Company	OWN	
152.30	Ream, J., M. Bailey, J. Leach and S. Padgett (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949.	436433-04	Monsanto Company	OWN	
152-30 185.3050 885.4150	Bechtel, C. L. (1999). Acute Oral Toxicity of B.t. Protein 11231 in Mice. Monsanto Technical Report MSL-16216.	449043-05	Monsanto Company	OWN	
152.30	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgett (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12: 92-419-719.	436919-01	Monsanto Company	OWN	

Signature *Natalia N. Bogdanova* Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager Date September 29, 2006

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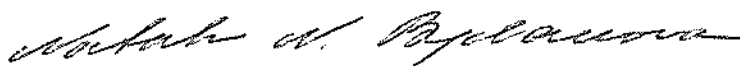
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Pitler, C. D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3.	453613-03	Monsanto Company	OWN	
153-4 885.2500	Hofschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.t1098 and NPTII Proteins in Corn Event MON 863 to Microbial Sources. Technical Report MSL-17220.	454240-05	Monsanto Company	OWN	
885.3050	Kapadia, S. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the CryIA.t05 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.		Monsanto Company	OWN	
	Vaughn, T. T., M. Pleau, R. Knutson and T. Coonice (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (<i>Diabrotica barberi</i>), Southern Corn Rootworm (<i>D. undecimpunctata howardi</i>), and Western Corn Rootworm (<i>D. virgifera virgifera</i>). MTC RPT4.	455382-08	Monsanto Company	OWN	
	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McPerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Control Product. Monsanto Technical Report MSL-17556.	455770-01	Monsanto Company	OWN	
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Guideline Reference Number	Guideline Study Name	MRIQ Number	Submitter	Status	Note
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in MON 863. Monsanto Technical Report MSL-17766.	456530-01	Monsanto Company	OWN	
	Mitchell, P. D. (2002). Yield Benefit of MON 863. Monsanto Technical Report MSL-17782.	456530-02	Monsanto Company	OWN	
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - Yield [®] Rootworm. MSL-17993.	456923-01	Monsanto Company	OWN	
	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. Monsanto Technical Report MSL-17243.	459415-01	Monsanto Company	OWN	
	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4.	459438-01	Monsanto Company	OWN	
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Data Waiver Request: Toxicity of <i>B.t.</i> Cry3Bb1 Protein in the Red Milkweed Beetle (<i>Tetropoes</i> sp.). Monsanto Technical Report MSL-18741.		Monsanto Company	OWN	
151-20, 153-4 885.1100 885.2200	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. Monsanto Technical Report MSL-17223.	454240-07	Monsanto Company	OWN	
	Dudin, Y. A., B-P. Tonini, L. D. Albee, and R. P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Tissue Samples Collected From Corn Event MON 863 Grown in 1999 Field Trials. Monsanto Technical Report MSL-17181.	451568-02	Monsanto Company	OWN	
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500 885.2200 885.2400 885.2500	Dudin, Y., B-P. Tonini and R. P. Lirette (2001). Cry3Bb1, Cry1Ab and NPTII Protein Levels in the Dual-trait Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. Monsanto Technical Report MSL-17266.	457917-02	Monsanto Company	OWN	

Signature

Name and Title

Natalia N. Bogdanova, DVM
Regulatory Affairs Manager

Date

September 29, 2006

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30 185.3050 885.4150	Bechtel, C. L. (1999). Acute Oral toxicity of <i>B.t.</i> Protein 11098 in Mice. Monsanto Technical Report MSL-16215.	449043-06	Monsanto Company	OWN	
151-36 885.2200	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of <i>B.t.</i> Protein 11098 and <i>B.t.</i> Protein 11231 Sequences Utilizing Toxin and Public Domain Genetic Databases. Technical Report MSL-15870.	449043-08	Monsanto Company	OWN	
151-36 885.2200	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of <i>B.t.</i> Protein 11098 and <i>B.t.</i> Protein 11231 Sequences Utilizing an Allergen Database. Technical Report MSL-15873.	449043-09	Monsanto Company	OWN	
152.30	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the <i>In Vitro</i> Digestibility of <i>B.t.</i> protein 11098 and <i>B.t.</i> 11231 Utilizing Mammalian Digestive Fate Models. Technical Report MSL-17166.	454240-06	Monsanto Company	OWN	
153-4 885.2500	Holteschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of <i>B.t.</i> Protein 11098, <i>B.t.</i> Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources. Technical Report MSL-17222.	454240-04	Monsanto Company	OWN	
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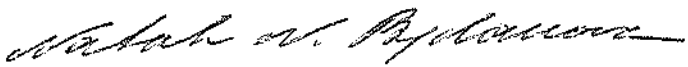
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1300 885.2100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masucci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068.	46694501	Monsanto Company	OWN	
885.1300 885.2100 885.2200	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the CryIA.105 Protein Utilizing the AD5, TOXINS, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	46694605	Monsanto Company	OWN	
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to <i>Collembole (Folsomia candida)</i> . Monsanto Technical Report MSL-16174.	45086314	Monsanto Company	OWN	
885.1100 885.2100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the CryIA.105 Protein to CryIA Class of <i>Bacillus thuringiensis</i> Proteins. Monsanto Technical Report 05-RA-62-01.	46694601	Monsanto Company	OWN	
Signature 			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 29, 2006	

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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

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Ingredient: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1300 885.2100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masocci. 2005. Summary of Southern blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068.	466945-01	Monsanto Company	OWN	
885.1300 885.2100 885.2200	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cry1A.105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Company	OWN	
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to <i>Collenibola (Folsomia candida)</i> . Amended report. Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	OWN	
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). Monsanto Technical Report MSL-16173.	450863-10	Monsanto Company	OWN	
885.1100 885.2100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the Cry1A.105 Protein to Cry1A Class of <i>Bacillus thuringiensis</i> Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Company	OWN	
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date September 29, 2006

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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167
Product: MON 89034 x MON 88017
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZM1R245 and PV-ZM1R39) Necessary for their Production in MON 89034 x MON 88017

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Signature *Natalia N. Bogdanova* Name and Title
Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager Date
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			Monsanto Company	OWN	
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Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017		

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Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date September 29, 2006

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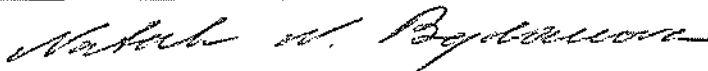
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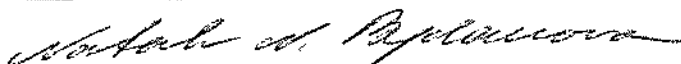
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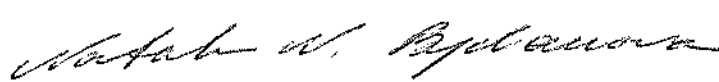
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			Monsanto Company	OWN	
Signature			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager		Date September 29, 2006

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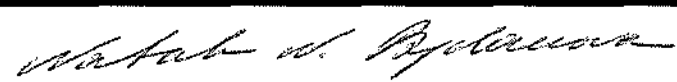
Page 10 of
25

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
Signature			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager		Date September 29, 2006

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

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Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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			Monsanto Company	OWN	
			Monsanto Company	OWN	
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Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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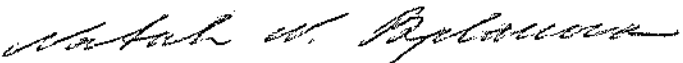
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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			Monsanto Company	OWN	
Signature			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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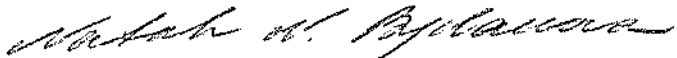
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
Signature			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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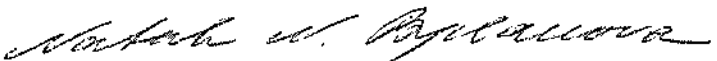
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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Signature			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167
Product: MON 89034 x MON 88017
Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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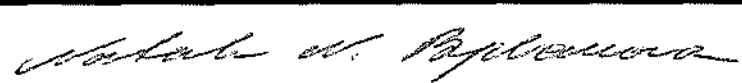
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017
Ingredient Bacillus thuringiensis Cry I A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	
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			Monsanto Company	OWN	
Signature			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZM1R245 and PV-ZM1R39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	

Signature

Name and Title

Natalia N. Bogdanova, DVM
Regulatory Affairs Manager

Date

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017					
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			Monsanto Company	OWN	
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Signature <i>Natalia N. Bogdanova</i>		Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager		Date September 29, 2006	

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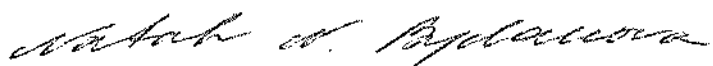
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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			Monsanto Company	OWN	
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Signature			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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			Monsanto Company	OWN	
			Monsanto Company	OWN	

Signature

Natalia N. Bogdanova

Name and Title

Natalia N. Bogdanova, DVM
Regulatory Affairs Manager

Date

September 29, 2006

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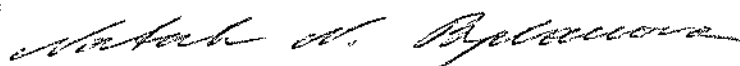
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

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Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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			Monsanto Company	OWN	
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Signature			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager		Date September 29, 2006

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Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

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			Monsanto Company	OWN	
Signature <i>Natalia N. Bogdanova</i>			Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 29, 2006	

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: September 29, 2006

EPA Reg. No./File Symbol: 524-XXX

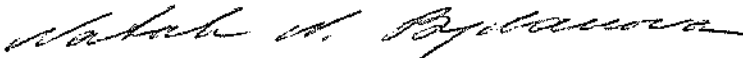
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x MON 88017

Ingredient Bacillus thuringiensis CryIA.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material (Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x MON 88017

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
Signature			Name and Title Natalia N. Bogdanova, DVM Regulatory Affairs Manager	Date September 29, 2006	

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Monsanto Company

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SECTION II

SUMMARY OF THE APPLICATION

This application contains eight volumes which support the safety of MON 89034 X 88017 developed by combining MON 89034 and MON 88017 by traditional breeding. Volume 1 contains the administrative materials. Volume 2 contains the human health and environmental assessment. Volumes 3 – 7 contain information on product characterization and efficacy. Volume 8 contains the proposed IRM plan.

SECTION III

PRODUCT LABEL

The subject of this application is for the *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins and the genetic material (vectors PV-ZMIR245 and PV-ZMIR39) necessary for their production in MON 89034 x MON 88017, including field corn, popcorn, and sweet corn. A full and unrestricted FIFRA section 3 registration is being sought to support commercialization of this product. Two copies of the proposed label for MON 89034 x MON 88017 are attached.

Plant-Incorporated Protectant Label

MON 89034 x MON 88017

Lepidopteran-Protected Corn

(OECD Unique Identifier: MON-89034-3 x MON-88017-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn0.0031 - 0.0084%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0030 – 0.0057%

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn0.0037 – 0.0070%

*Percent (wt/wt) on a dry weight basis in whole plant (forage)

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-xxx

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

Information regarding commercial production to be included in the Grower Guide for Cotton-Growing and Non-Cotton Growing Areas.

Plant-Incorporated Protectant Label

MON 89034 x MON 88017

Lepidopteran-Protected Corn

(OECD Unique Identifier: MON-89034-3 x MON-88017-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn0.0031 - 0.0084%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0030 - 0.0057%

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn0.0037 - 0.0070%

*Percent (wt/wt) on a dry weight basis in whole plant (forage)

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-xxx

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

Information regarding commercial production to be included in the Grower Guide for Cotton-Growing and Non-Cotton Growing Areas.

SECTION IV

PRODUCT ANALYSIS

Studies referenced in the data matrix included in this application (Volumes 3-6) describe a) the health and environmental assessment of MON 89034 x MON 88017, b) the molecular identity of MON 89034 x MON 88017, and c) the levels of the Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins produced in tissues of MON 89034 x MON 88017.

SECTION V

RESIDUE DATA

EPA has established an exemption from the requirement of a tolerance for plant-incorporated protectants and inert ingredients produced by MON 89034 x MON 88017; therefore, residue data are not required for this product.

SECTION VI

NONTARGET ORGANISM DATA

Studies have been conducted by Monsanto to characterize the potential hazards to NTOs result from exposure to the Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins. Reports for relevant studies previously submitted to EPA are referenced in the data matrix. The environmental assessment of the Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins produced in MON 89034 x MON 88017 is described in Volume 2 of this application.

SECTION VII

TOXICOLOGY DATA

Studies conducted to assess the potential toxicity and allergenicity of the Cry1A.105 and Cry2Ab2 proteins have previously been submitted to EPA and are referenced in the data matrix.

SECTION VIII

EFFICACY DATA

Data assessing the efficacy of the Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins produced in MON 89034 x MON 88017 are presented in Volume 5 of this application.

FOR OFFICIAL USE ONLY

FILE SYMBOL

524-LTA

REGISTRATION NO.

389

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
9/29/06		

**Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope**

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

EPA Registration File No. 524-576 Vol. # 1.

Page _____ is not included in this copy.

Pages 390 through 394 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

X The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-client communication.

_____ Claimed confidential by submitter upon submission to the Agency.

_____ Third party confidential business information.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

VOLUME 1

Administrative Materials for the Application to Register the Plant-Incorporated Protectant,
Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 Proteins and the Genetic Material
(Vectors PV-ZMIR245 and PV-ZMIR39) Necessary for their Production in MON 89034 x
MON 88017

(OECD Unique Identifier: MON-89034-3 x MON-88017-3)

EPA File 524 - XXX

CONFIDENTIAL ATTACHMENT

AUTHOR

Natalia N. Bogdanova, D.V.M.
Regulatory Affairs Manager

SUBMISSION DATE

September 29, 2006

SUBMITTING REGISTRANT

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

MONSANTO REFERENCE NO.

06-CR-177E-1

CONFIDENTIAL BUSINESS INFORMATION

CBI Cross Reference Number 1

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

<u>Page</u>	<u>Reason for Deletion</u>	<u>FIFRA Reference</u>
8	Discloses confidential commercial business information	

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